

# COVINGTON & BURLING

1201 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004-2401  
TEL 202.662.6000  
FAX 202.662.6291  
WWW.COV.COM

WASHINGTON  
NEW YORK  
LONDON  
BRUSSELS  
SAN FRANCISCO

1219 04 MAY -a 12:12

May 4, 2004

## By Hand Delivery

Dr. Richard Carmona  
United States Department of Health and Human Services  
Task Force on Importation  
Division of Dockets Mgmt (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 2004N-0115

Dear Dr. Carmona and Members of the HHS Task Force on Importation,

Enclosed please find comments to Docket No. 2004N-0115 of the United States Department of Health and Human Services ("HHS") Task Force on Importation related to the study HHS is required to conduct under Section 1122 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Public Law 108-173). These comments address the regulation of prescription drugs by foreign health agencies.

As described in the Conference Report that accompanied H.R. 1 and the MMA, the study required under Section 1122 should include a consideration of "the extent to which foreign health agencies are willing and/or able to ensure the safety of drugs being exported from their country into the United States, including drugs that are transshipped through their countries." H.R. Conf. Rep. No. 108-391, at 834 (2003). The enclosed analysis, conducted by Covington & Burling on behalf of various clients with an interest in these matters, is directly relevant to that question.

We examined the laws and regulations of 25 countries relating to export and transshipment. While all of the surveyed countries impose regulatory requirements related to the domestic distribution and sale of pharmaceutical products, almost all countries impose a lesser level of regulation on products intended for export to other countries, such as the United States, and most countries do not regulate products that are merely transshipped through their territory. The results of the survey demonstrate that the laws in many of the countries surveyed cannot guarantee the safety, quality or efficacy of products exported to the United States.

2004N-0115


C6

COVINGTON & BURLING

Dr. Richard Carmona  
Docket No. 2004N-0115  
Page 2

We appreciate the Task Force's consideration of these comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard Kingham".

Richard Kingham  
Michael S. Labson  
Grant Castle

Enclosure

April 21, 2004

## **Regulation of Medicinal Products Intended for Export**

Twenty-five countries have been identified as potential sources of pharmaceutical products to be imported for use in the United States market. This memorandum contains the results of a survey of the laws, guidelines, and practices governing the export of medicinal products in those 25 jurisdictions.

The survey was formatted as a series of questions. We summarize the responses for each jurisdiction in the attached table. We also attach the full response for each jurisdiction in the Appendix to this memorandum. We have identified the local counsel who have provided responses, where relevant. All other responses have been prepared by Covington & Burling.

This memorandum considers only the rules governing general medicinal products, and not those governing products that may be subject to additional regulation, such as narcotic, psychotropic or other controlled substances.

The results of the survey demonstrate that the laws in many of the countries surveyed cannot guarantee the safety, quality or efficacy of products exported to the United States.

### **1. General Regulation of Exported Product**

Countries generally require pharmaceutical products to meet one or more of three types of regulatory requirements: authorization to place the product on the market, authorization to manufacture the product, and authorization to distribute the product. While all of the surveyed countries impose regulatory requirements related to domestic distribution and sale of pharmaceutical products, most countries impose a lesser level of regulation on products that are intended only for export to other countries such as the United States.

Entities distributing or manufacturing products domestically must usually hold government authorizations and comply with good manufacturing practices ("GMP") or good distribution practices ("GDP"), as appropriate. However, these controls often do not apply for the manufacture or distribution of products for export only. Most countries do not regulate products that are merely trans-shipped through their territory.

#### **1.1 Marketing Authorization and Related Requirements**

The countries surveyed all imposed a marketing authorization requirement on products intended for their domestic markets. In most cases, the marketing authorization requirement is triggered only if the product is "placed on the market," "supplied," "sold," or "distributed" within the relevant jurisdiction.

While countries such as Australia, Austria, Denmark, France, Japan and Spain impose additional administrative controls on the import or export of drug products, only a few countries require that a product be authorized in the country before import or export. This means that there may

be little or no regulatory assessment of the safety, efficacy and quality of imported and/or exported products. Canada, Germany, Ireland, Israel, Luxembourg, and Switzerland require marketing authorizations prior to the import of products. In the case of Canada, Israel, Luxembourg, and Switzerland, this results from a broad definition of terms such as "sell" or "distribute." Luxembourg and Norway require a marketing authorization in order to export a product.

While Australia does not require a marketing authorization, the product must be listed on the Australian Register of Therapeutic Goods prior to both import and export. Switzerland does not require a marketing authorization for export, but places certain restrictions on exported products. Danish and French regulatory authorities may request that exporters explain why exported products are not subject to a national marketing authorization. Israel requires proof that an exported product is either registered or approved for import in the destination country.

Austria requires prior authorization by the Ministry of Health and Women for the import of product from outside the European Economic Area ("EEA"), and requires products intended only for export to be stored separately from other products. Spain requires notification to the Spanish Medicines Agency of the import of product subject to a Spanish marketing authorization. However, prior authorization is necessary if the product is not subject to a Spanish marketing authorization. Japan has imposed a prior notification requirement on products imported or manufactured for export only. Portugal requires exporters to display both a wholesaling license and a Portuguese marketing authorization or manufacturer's authorization. For products that have been imported for export only, Portuguese officials will accept a marketing authorization or manufacturing authorization from the source country.

## **1.2 Manufacturing Authorization**

The majority of countries require a manufacturer's authorization for the manufacture of medicinal products. The term "manufacture" normally includes any processing, assembly, packaging, labeling, and storage of the product. Most also consider the importation of product to be a manufacturing operation, although the EEA member states only treat importation from outside the EEA as manufacturing.

All of the surveyed countries require a manufacturer's authorization even if the product is manufactured only for export. In most countries, the holders of manufacturing authorizations must manufacture products for export in accordance with the same standard of GMP that applies to products for domestic sale. However, products manufactured for export in Germany, Israel, and New Zealand may be subject to less stringent requirements. Canada provides a complete exemption from national regulation and control where product is fabricated solely for export.

Furthermore, each country's GMP requirements may differ from their American equivalents. There are currently moves towards the international harmonization of GMP, but these are limited in scope. For example, the International Conference on Harmonization ("ICH") has developed standards for the manufacture of active pharmaceutical ingredients, but many jurisdictions, including the EC, have yet to adopt them formally. Other standards, including those for the manufacture of starting materials, inactive ingredients and of finished medicinal products, are also not yet harmonized.

While mutual recognition agreements (“MRAs”) could allow the United States to rely on another country’s GMP inspections, the variability in national requirements means that the United States has yet to enter into working MRAs with any of the surveyed countries. The United States has agreed to share certain GMP inspection and enforcement information with countries such as Australia, Canada and Japan, but has not executed full MRAs. While the United States executed an MRA with the EC in 1997, it has yet to implement it.

### **1.3 Distribution Authorization**

Australia, Austria, Canada, Germany,<sup>1</sup> Greece, Israel, and New Zealand do not always require a wholesaler’s or distributor’s license for the distribution of product intended for export. The UK also exempts some importers from licensing requirements. The other countries require such a license, and expect authorized distributors to operate in accordance with GDP. Again, the standards of GDP vary. Canada, for example, requires that distribution be conducted in accordance with applicable provisions of GMP, unless the product benefits from the Canadian exemption for product intended solely for export.

## **2. Regulation of Trans-Shipped Product**

Products imported solely for re-export (“trans-shipped products”) are not subject to any regulatory control, oversight, or supervision in a number of countries. For ease of reference, these countries are shaded in the attached table.

Some jurisdictions expressly exclude trans-shipped products from the scope of their national rules. In Austria, Finland, Israel, and Liechtenstein, the exemption appears to be without limitation. In Australia, Greece, Iceland, South Africa, and the UK, the exemption only applies if no manufacturing operations are performed during trans-shipment. France, Luxembourg, the Netherlands and South Africa require that trans-shipped products be stored in customs warehouses. Switzerland does not regulate trans-shipped products, but considers products stored in Swiss customs warehouses to have been imported, and therefore subject to Swiss regulation. Products trans-shipped through Canada may benefit from an exemption from national regulation and control under certain circumstances.

Only Norway requires trans-shipped products to meet the same requirements as products on the domestic market. Other countries do not require that the products hold marketing authorizations, but may require businesses to hold manufacturing or distribution licenses in order to engage in trans-shipping activities.

## **3. Discussion**

Most of the countries surveyed imposed a degree of regulatory control over products placed on the market in their territory and subsequently exported. Entities distributing or manufacturing such products must usually hold government authorizations and comply with varying standards

---

<sup>1</sup> Germany is in the process of amending its national laws to bring such products within the scope of its wholesale distribution regulations.

of GMP or GDP, as appropriate. However, in a number of jurisdictions, including Australia, Austria, Germany, Greece, Ireland, Israel, Italy, Luxembourg, New Zealand, and the UK, such controls do not necessarily apply. In addition, Canada offers a formal exemption for products intended only for export. It is possible that products could be exported from these jurisdictions to the United States without full regulatory control or oversight.

There is a more pronounced lack of regulation of products that are trans-shipped *via* the surveyed jurisdictions. There is no guarantee that products trans-shipped through most jurisdictions would be subject to correct handling and storage. All of the surveyed countries except Norway either expressly or implicitly exclude some trans-shipped products from coverage under their laws. Thus, products trans-shipped through most of the surveyed countries will not have to meet the same standards that would be required of a product introduced onto the domestic market.

Furthermore, the countries that do not expressly exempt trans-shipped products from the legal requirements applying to domestic medicinal products may not actively enforce their laws against trans-shipped products. These products may not represent a significant enforcement priority, when the relevant agency has limited enforcement resources. In fact, the regulators in Canada, Japan, Luxembourg, and New Zealand admitted that this might be the case.

Some practices allowed by these countries may result in dangerous pharmaceutical products entering foreign markets, including the United States. Under Japanese law, for instance, it is lawful to import or domestically procure out-of-date medical products, re-package them as new products, and export them to foreign destinations. Such practice would become unlawful only when the Japanese government deems the products to be "decomposed" or otherwise harmful. Yet the United States government would deem these products to be potentially harmful by the very fact of being out-of-date.

Furthermore, the South African government can explicitly allow the entry of some "gray market" goods into that country. Those medicines have the same name as a registered product, and are deemed to be identical in composition to, and meet the same quality standards as, the registered medicine. However, these medicines are imported (and possibly manufactured) by an entity other than the manufacturer named in the official product registration, which could have implications for product safety, efficacy, and accountability.

## Summary of Survey Results

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Australia</b>  Therapeutic Goods Act 1989 ("Act"); Therapeutic Goods Regulations 1990 ("Regs"), (together "TG Legislation"); TGA Code for Good Wholesaling Practice ("Code").  Administered by the Therapeutic Goods Administration ("TGA").	<p>No, MA is not required for <i>import</i> of product, <u>but</u> if not either approved or exempt from approval requirement, product must be registered on the Australian Register of Therapeutic Goods ("ARTG") (Act).</p> <p>Yes, "sponsor"<sup>1</sup> must have MA to <i>supply</i> products, whether they are manufactured in Australia or imported.</p> <p>No, MA is not required for products intended solely for <i>export</i>, <u>but</u> they are accepted for listing on the ARTG (whether imported into or manufactured in Australia).</p>	<p>a) Yes, license is required for "manufacture,"<sup>2</sup> whether product intended for export or not (Act).</p> <p>b) Yes (Act). (Products manufactured outside Australia must provide evidence of "GMP clearance of overseas manufacturers").</p>	<p>a) No, TG Legislation does not require distributors to hold a license,<sup>3</sup> <u>but</u> States usually require a Wholesaler's License for supply by wholesale.</p> <p>b) Yes (Code).</p>	No. <sup>4</sup>	<p>No. Trans-shipment is not regulated (i.e. is not treated as an import/export) if it involves no "manufacture," is part of a continuous carriage within the control of a single person, and goods do not clear customs.</p>	<p>Because no laws apply to trans-shipped products, there is no enforcement.</p> <p>For exports, TGA will actively enforce rules, particularly if non-sponsors export products.</p>

<sup>1</sup> "Sponsor" is a person who exports medicines out of or imports medicines into Australia, or who manufactures medicines in Australia, but excludes a person who undertakes these activities on behalf of a person who is a resident of Australia or who is carrying on business in Australia (in which case, that person would be the sponsor).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Austria</b>  Medicines Law, <i>Arzneimittelgesetz</i> ("AMG"); Law on the Importation of Medicinal Products, <i>Arzneiwareneinfuhrgesetz</i> ("AWFG"); Industrial Code; Regulation applicable to Manufacturers, Depositors and Wholesalers ("Regulation").  Administered by the Ministry of Health and Women ("Ministry").	No, MA is not required for import of product. Authorization required to <b>import</b> product from a non-EEA country. Import of product from an EEA country must be notified to the Ministry (AWFG).  Yes, MA is required for " <b>placing on the market</b> ." <sup>5</sup>  No, MA is not required for products intended for <b>export</b> , if stored separately from other products. <sup>6</sup>	a) Yes, license is required for "manufacturing" <sup>7</sup> (AMG).  b) Yes (Regulation).	a) No. License is not required for export <i>per se</i> , but wholesale license is required for "placing on the market," which includes storage.  b) Yes, wholesalers must comply with the Industrial Code and the Regulation.	No.  (See footnote 4.)	No. Trans-shipped products are not covered by the AMG (such products are not "placed on the market") or the AWFG (which specifically states that trans-shipping is not considered to be importation, and that no import approval is needed).	Because no laws apply to trans-shipped products, there is no enforcement.  Licensed manufacturers and wholesalers subject to inspections.

<sup>2</sup> "Manufacture" is defined in the Act to mean production of medicines, or engaging in any part of the process of producing the medicines to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the medicines or of any component or ingredient of the medicines as part of that process.

<sup>3</sup> Storage and distribution activities may fall within the definition of "manufacture," however, and thus require a license under section 35 of the Act.

<sup>4</sup> Australia, Austria, Belgium, Denmark, Germany, Greece, Israel, Italy, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, South Africa, Sweden, Switzerland, and the UK impose pre-notification or pre-approval requirements related to narcotic, psychotropic, or other controlled substances.

<sup>5</sup> "Placing on the market" is defined as the "storage, the keeping available or the delivery of medicinal products" (s11 of the AMG).

<sup>6</sup> Products are not "placed on the market" if they are stored in such a way as to guarantee that no final consumer or user has access to the products (s2(11) of the AMG).

<sup>7</sup> "Manufacturing" is defined as "the extracting, the producing, the preparing, the finishing, the processing, the transfer in other containers, bottles, etc., and the packaging of medicinal products as well as the labeling."

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Belgium</b>  Medicines Law of 17 April 1964 ("Law"); Decree on the Manufacturing, Distribution and Supply of Medicines of 6 June 1960 ("1960 Decree"); Ministerial Decree of 17 October 1995 ("1995 Decree").  Administered by the DG Public Health Protection: Medicinal Products.	No, MA is not required for <i>import</i> of product.  Yes, MA is required for " <i>placing on the market.</i> "  No, MA is not required if wholesaling product for <i>export</i> purposes (not considered "placing on the market").	a) Yes, license is required for manufacture or assembly of a product, whether intended for export or not. <sup>8</sup>  b) Yes, whether product intended for export or not (1960 Decree).	a) Yes, license is required to distribute/export product (1960 Decree). (A manufacturing license allows the manufacturer to sell the product, but a separate license is required to export.)  b) Yes (1995 Decree).	No.  (See footnote 4.)	No. Product is not required to hold a MA. Importation of finished product from outside the EEA for re-export outside the EEA requires an import license, export license and compliance with GDP. If exporter does not hold a MA, he will also need to declare the medicines for inspection. A less restrictive regime will apply to any product or products imported only for export, if certain conditions are met. <sup>9</sup>	It is possible that companies focusing on import-export activities are subject to less rigorous controls.  The situation is unclear if products remain under customs control, as inspection services do not have access to such product.

<sup>8</sup> If the products are intended for export and not registered, the manufacturer must first supply additional information (a "declaration"), comparable to a simplified registration procedure, including the complete qualitative and quantitative composition and a complete chemical-pharmaceutical dossier.

<sup>9</sup> The medicines must be exported without any further processing or handling within Belgium; the products clearly must indicate the person responsible for the marketing of the products in the destination country and, if different, the manufacturer; and must not refer to any person established in Belgium.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Canada</b></p> <p>Food and Drugs Act, R.S.C. (1985), c.F-27 as amended ("Act"); Food and Drug Regulations, C.R.C., c.870 as amended ("Regs").</p> <p>Administered by the Health Products and Food Branch ("HPFB").</p>	<p>Yes, Notice of Compliance ("NOC") is required to <i>import</i> product, whether intended for re-export or not (see footnote 10).</p> <p>Yes, NOC is required for <i>sale</i><sup>10</sup> of product in Canada.</p> <p>No, NOC is not required <i>export</i> products that are intended only for export (exemption under s37 of the Act).</p>	<p>a) i) No, Establishment License ("EL") is not required by fabricator of product, intended for export, and invoking s37 of Act.</p> <p>ii) Yes, EL is required by importer of product, intended for re-export (Regs).</p> <p>b) i) No.</p> <p>ii) Yes, compliance with GMP is mandatory for holders of an EL.</p>	<p>a) N/A.</p> <p>b) N/A.</p>	<p>Yes.</p> <p>Fabricators must notify HPFB of products for which they are invoking the s37 exemption.</p> <p>HPFB will issue export certificates on request.</p>	<p>No. Under the section 37 exemption, a NOC may not be required for products that are prepared in Canada for the destination market, e.g. by repackaging or relabeling. Products exported under this exemption fall outside the scope of the Act and Regulations.</p>	<p>Products exempted under section 37(1) are not subject to the Act or Regs. There is anecdotal evidence of reduced scrutiny of products intended for export.</p>

<sup>10</sup> Section 2 of the Act defines the term "sell" to include "offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration."

## COVINGTON &amp; BURLING

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Denmark</b>  Medicinal Products Act ("Act"); Executive Order on GMP and GDP Practice for Medicinal Products (EO No. 264 of 4 April 1997) ("Order"); Ministry for the Interior and Health's Circular No. 14 of 29 January 1998 ("Circular").  Administered by the Danish Medicines Agency ("Agency").	No, MA is not required to <i>import</i> product. Products imported from outside EEA require an authorization similar to a manufacturer's authorization.  Yes, MA is required for <i>sale</i> of product.  No, MA is not required prior to <i>export</i> of product. (Under the Act, authorized manufacturers and exporters must, on request, provide the Agency with the reasons for not having applied for a MA.)	a) Yes, manufacturing authorization is required to manufacture or pack product, whether intended for export or not (Act). Manufacturing authorization also covers storage and wholesale trade.  b) Yes (Order). <sup>11</sup>	a) Yes, a distributor authorization is required. This allows storing and exporting of products, as well as wholesale trade.  b) Yes (Order).	No.  Voluntary listing in export register.  (See footnote 4.)	No. MA is not required for trans-shipped products, but must comply with licensing regulations for both import and export.	Trans-shipped products are not subject to enforcement of MA requirements.  Otherwise, regulations governing exported products are administered in the same way as other medicinal products rules.

<sup>11</sup> Section 1(2) of the Order states that the Order regulates import and manufacture of medicinal products, including manufacture for export. Part 4 of the Order sets out regulations on import.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Finland</b>  Medicines Act (395/1987) ("Act"); Medicines Decree (693/1987) ("Decree").  Administered by the National Agency for Medicines ("NAM").	No, MA is not required for <i>import</i> of product.  <b>Yes</b> , MA is required if products are <i>sold</i> to the public or otherwise released for consumption.  No, MA is not required for <i>export</i> of products.	a) <b>Yes</b> , license is required if manufacture product, whether intended for export or not.  b) <b>Yes</b> , whether product is intended for export or not.	a) <b>Yes</b> . Distributors/exporters must hold a government license for manufacture or wholesale distribution; a separate license is not required for export.  b) <b>Yes</b> .	<b>No</b> .	<b>No</b> . Under the general rules, a product may be trans-shipped <i>via</i> Finland without obtaining any license or permit from the NAM or any other authority.	Because no laws apply to trans-shipped products, there is no enforcement.  For exports, product destination does not affect the level of supervision.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>France</b></p> <p>French Public Health Code, <i>Code de la santé publique</i> ("CSP"); Ministerial ordinance of 10 May 1995 on GMP ("GMP Ordinance"); Ministerial ordinance of 30 June 2000 on good wholesale distribution practices ("GDP Ordinance").</p> <p>Administered by the Medicines Agency, <i>Agence Française de Sécurité Sanitaire et des Produits de Santé</i> ("AFSSAPS").</p>	<p>No, MA is not required prior to <b>import</b> of product, <b>but</b> a MA does exempt importer from obtaining an import authorization (CSP).</p> <p>Yes, MA is required before a product can be <b>marketed or distributed</b> in France (transferred to a third party) (CSP).</p> <p>No, MA is not required to <b>export</b> product. However, for product without MA, the exporter must also notify the AFSSAPS of the reasons why the MA is not available. Also see column 5.</p>	<p>a) Yes, authorization is required for product manufacture,<sup>12</sup> whether intended for export or not (CSP).</p> <p>b) Yes (GMP Ordinance). Evidence of GMP compliance is required for products imported from a country outside the EU/EEA (CSP).</p>	<p>a) Yes, wholesale dealers must be authorized (CSP).</p> <p>b) Yes (GDP Ordinance and CSP).</p>	<p><b>Yes.</b></p> <p>Must have AFSSAPS certification that exporter is authorized pharmaceutical establishment (CSP). Also see column 1.</p>	<p><b>No.</b> Trans-shipped products are subject to separate rules.</p> <p>Medicines stored in a national import warehouse (pursuant to the General Tax Code), as well as unfinished products, require an import authorization.</p> <p>CSP does not distinguish between import from EEA countries and import from non-EEA countries. However, an AFSSAPS official stated that products are not subject to the CSP if they are imported from non-EEA countries for export to non-EEA countries and remain in a customs warehouse.</p>	<p>Even though different rule may apply, no evidence suggests that inspections or enforcement activities are less rigorous when product is intended only for export.</p>

<sup>12</sup> "Manufacturing" includes purchase of raw material and conditioning material, production, quality control, release of batches, and related storage activities. Manufacturers may not import finished product, but only raw materials and conditioning materials, unless they hold an import authorization, in addition to the manufacturing authorization.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Germany</b></p> <p>Medicines Law, <i>Arzneimittelgesetz</i> ("AMG"); Announcement of GMP guidelines for pharmaceutical products of the pharmaceutical inspection convention ("PIC Guidelines").</p> <p>Administered by the Federal Institute for Medicinal Products and Medical Devices, <i>Bundesinstitut für Arzneimittel, und Medizinprodukte</i> ("BfArM"), except for immunological products, vaccines and blood products, which are regulated by the <i>Paul Ehrlich Institut</i> ("PEI"). The regional authorities issue manufacturing licenses.</p>	<p>Yes, MA is required for <i>import</i> of product.<sup>13</sup></p> <p>Yes, MA is required for "<i>placing on the market</i>" (covers wholesale distribution) (AMG).</p> <p>No, MA is not required if product is intended solely for <i>export</i> (AMG).</p>	<p>a) Yes, authorization is required to manufacture or assemble any product, even if intended only for export (AMG).</p> <p>b) No. Domestic products must comply, but products for export are subject to more relaxed rules (PIC Guidelines and AMG).<sup>14</sup></p>	<p>a) No, license is not required currently, <u>but</u> draft AMG amendment will require wholesaler's license to export product.</p> <p>b) No, <u>but</u> amended AMG will require compliance with GDP.</p>	<p>No.</p> <p>(See footnote 4.)</p>	<p>No. Importation of trans-shipped product does not require a MA (exempt under AMG).<sup>15</sup> Product still must comply with lower GMP standard (see footnote 14) and not be unsafe.</p>	<p>Trans-shipped products are not subject to enforcement of MA requirements.</p> <p>There is no evidence to suggest that licensing inspections or enforcement activities are less rigorous when product is intended only for export.</p>

<sup>13</sup> Products for personal use and limited samples for analytical tests and for official batch testing are exempt from this requirement.

<sup>14</sup> Article 8 of the AMG prohibits manufacturing of products that "by deviating from recognized pharmaceutical principles, are significantly diminished in their quality." Significant deviations from GMP could result in diminished quality. Article 5 of the AMD prohibits the marketing of unsafe products. Deviations from these standards also are allowed if the competent authority in an importing country agrees to the import of diminished product (Art. 73a of the AMG).

<sup>15</sup> The exemption in Article 73(2) of the AMG applies to (i) products transported under supervision of the customs authorities and (ii) products exported after transit storage in customs depots or bonded warehouses.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p>Greece</p> <p>Law 1316/1983 on the "Foundation, organization and authorities of the National Drug Organization etc" ("Law"); Ministerial Decision A6a/9392/91/92 ("Decision 91/92"); Legislative Decree No 96/1973 ("Decree"); Ministerial Decision A6a/9392/1991 ("Decision 1991"); Ministerial Decision Y6/11228/1992 (Decision 1992"); Circular No. 40033/2001 ("Circular"); Ministerial Decision Y6/2610/1993 ("Decision 1993").</p> <p>Administered by the National Drug Organization ("EOF").</p>	<p>No, a circulation license ("CL") is not required for <i>import</i> of product.</p> <p>Yes, a CL is required before product (either locally produced or imported) is <i>supplied or marketed</i> in Greece (Decision 91/92).</p> <p>No, a CL is not required for products intended solely for <i>export</i>.</p>	<p>a) Yes, a license is required to manufacture or assemble a product, whether intended for export or not (Decision 91/92).</p> <p>b) Yes, whether product is intended for export or not (Decision 91/92 and Decision 1992).</p>	<p>a) No,<sup>16</sup> <u>but</u> must maintain records for receiving, controlling, and distributing products (Law); report quarterly to EOF (Circular). For product transported to or from other EU Member States, must inform EOF within 5 days of product arrival in Greece (Decision 1993).</p> <p>b) No.</p>	<p>No.</p> <p>(See footnote 4.)</p>	<p>No. Trans-shipped products are not regulated if they are not subject to any "manufacturing alteration."</p>	<p>Because no laws apply to trans-shipped products, there is no enforcement.</p> <p>For exports, no evidence suggests that licensing inspections or enforcement is less rigorous when product is intended only for export.</p>

<sup>16</sup> Wholesalers must be licensed in order to distribute product.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Iceland</b>  Medicinal Products Act No 93/1994 ("Act"); Regulation No 462/2000 ("2000 Regs"); Regulation on Manufacturing of Medicinal Products No 700/1996 ("Manufacture Regs"); Regulation on Import and Wholesale Distribution of Medicinal Products No 699/1996 ("Distribution Regs").  Administered by the Medicines Control Agency ("MCA").	<p>No, MA is not required for <i>import</i> of product.</p> <p>Yes, MA is required before a product can be <i>supplied or marketed</i> in Iceland (Act).<sup>17</sup></p> <p>No, a MA is not required for products intended solely for <i>export</i>.</p>	<p>a) Yes, a manufacturer's license is required for manufacture or assembly, whether the product is intended for export, or not (Act). Importation of a product from outside the EEA is a manufacturing operation requiring a wholesale dealer's import license (Distribution Regs).</p> <p>b) Yes (Manufacture Regs).</p>	<p>a) Yes, wholesale dealing license is required to export product for sale or supply (Act).</p> <p>b) Yes (Distribution Regs).</p>	No.	<p>No. Trans-shipment is not subject to licensing or oversight, unless products are subject to manufacturing. Product need not hold a MA.</p> <p>Manufacturing license is required to trans-ship a product imported from outside the EEA (see column 3).</p>	<p>Trans-shipped products are not subject to regulations or enforcement.</p> <p>For products manufactured in Iceland for export, there is no evidence to suggest that enforcement of manufacturing and distribution activities is less rigorous than for domestic products.</p>

<sup>17</sup> No product can be placed on the market or distributed by way of wholesale dealing without a MA. The term "wholesale dealing" encompasses the sale of a medicinal product in the course of a business, to a person who buys it for sale or supply, or for administration to a human being. The term "place on the market" is not defined under Icelandic law, but it is generally understood to involve to transfer of product to a third party.

## COVINGTON &amp; BURLING

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Ireland</b>  Medicinal Products (Licensing and Sale) Regulations (S.I. 142 of 1998 as amended ("Sale Regs"); Medicinal Products (Licensing of Manufacture) Regulations (S.I. 40 of 1993), as amended ("Manufacture Regs"); Medicinal Products (Wholesale Licenses) Regulations (S.I. 39 of 1993), as amended ("Wholesale Regs").  Administered by the Irish Medicines Board ("IMB").	<p>Yes, MA is required for <i>import</i> of product (Sale Regs).</p> <p>Yes, MA is required for <i>supply or marketing</i> of product in Ireland (Sale Regs).</p> <p>No, MA is not required where product is imported or sold solely for <i>export</i> (Sale Regs).</p>	<p>a) Yes, a license is required to "manufacture"<sup>18</sup> product for sale, even if intended only for export (Manufacture Regs). Importation of a product from outside the EC requires a manufacturer's license.</p> <p>b) Yes (Manufacture Regs).</p>	<p>a) Yes (Wholesale Regs) <u>but</u> importer or carrier agent of product imported from outside the EC/EEA need not hold a wholesaler's license if the products are delivered to a licensed manufacturer or wholesaler.<sup>19</sup></p> <p>b) Yes, for wholesale license holders (Wholesale Regs).</p>	No.	<p>No. Product is not required to hold a MA.</p> <p>Trans-shipped product imported from outside the EEA will require a manufacturing license.</p>	<p>Trans-shipped products are not subject to regulation or enforcement.</p> <p>For manufacturing and wholesale licensing requirements, no evidence suggests that inspections or enforcement activities are less rigorous for export-only products.</p>

<sup>18</sup> "Manufacture" includes total and partial manufacture; the various processes of dividing up, packaging or presentation; formulation, processing, compounding, or filling; and the importation of a medicinal product from a country other than an EC Member State.

<sup>19</sup> In this circumstance, a wholesaler's license is required if the import agent holds the product for an appreciable length of time (more than 48 hours).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Israel</b>  Pharmacopia Ordinance (New Version) 1981 ("Ordinance"); Pharmacists Regulations (Medicinal Preparations) 1986 ("Regs"); Procedure for the Registration of Medicinal Products 1991 ("Directive"); Notice regarding the terms for obtaining Manager's consent for exemption from registering product ("Notice"); Inspection Manual dated January 2003, adopting the GMP rules ("Manual").  Administered by the Ministry of Health ("Ministry").	<p>Yes, MA is required to <i>import</i> product.<sup>20</sup></p> <p>Yes, MA is required for the <i>sale or supply</i> of product.</p> <p>No, MA is not required to <i>export</i> product, <u>if</u> product is manufactured in Israel and intended for export, and Ministry's General Manager exempts it because it is safe for its intended purpose and either the product is registered in the destination territory, or the import is approved by the importing country's authorities (Regs and Notice).</p>	<p>a) Yes, a permit is required for the manufacture and packaging of product.</p> <p>b) Yes, whether product is intended for export or not (Manual).</p>	<p>a) No, exported product may be excluded from the permit requirement as described in column 2 (Regs and the Notice).</p> <p>b) No, but must transport and store the product appropriately.</p>	<p>No.</p> <p>If product is subject to a MA, no notification is required. If the product is not subject to a MA, the notification and approval described in column 2 is required. Also see footnote 4.</p>	<p>No. Trans-shipped products are not regulated and never enter Israel's jurisdiction.<sup>21</sup></p>	<p>There is no enforcement in Israel because trans-shipped products are not regulated. Products are not subject to any recognition, approval or inspection.</p> <p>The Manager may inspect permitted or suspected exporters for compliance with licensing requirements.</p>

<sup>20</sup> A marketing authorization is required for "marketing of product," which is defined in the Ordinance and the Regulations as "the sale, supply, import, export or the transfer of ownership or possession."

<sup>21</sup> Under the Paris Agreement, products trans-shipped to the Palestinian Authority *via* Israel are subject to Israeli inspection and approval.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Italy</b>  Legislative Decree 178/1991 as amended regulates manufacture of medicinal products ("1991 Decree"); Decree of the Ministry of Health of 1996 and of 2002 establish the requirements and procedure for obtaining a manufacturing authorization; Legislative Decree 583/1992 on the wholesale distribution of products ("1992 Decree"); Circular of the Ministry of Health of 1993 ("Circular").  Administered by the Italian Regions.	No, MA is not required to <i>import</i> product.  Yes, MA is required for the " <i>placing on the market</i> " of product, including imported product (1991 Decree).  No, MA is not required for product intended for <i>export</i> (1991 Decree).	a) Yes, a manufacturer's authorization is required for manufacture of product, whether intended for export, or not (1991 Decree, confirmed by Court of Appeal judgment in 2000). <sup>22</sup>  b) Yes (1991 Decree).	a) Yes, an authorization is required if a person keeps in warehouses, distributes or exports product (1992 Decree). <sup>23</sup>  b) Yes (Decree of the Ministry of Health of 1999).	No.  (See footnote 4.)	No. Product is not required to hold a MA. Importers and exporters, even of trans-shipped products, must meet manufacturing and distribution permit requirements.	No evidence to suggest that inspections or enforcement activities are less rigorous when product is intended only for export.

<sup>22</sup> Importers must obtain an authorization, even if the product will not be marketed in Italy (1991 Decree). The grant of an authorization is subject to compliance with quality manufacturing controls. However, an authorization is not required if (1) the product is imported from an EU Member State in which it was manufactured; (2) the product is imported from, but was not manufactured in, another EU Member State and that Member State has granted a certificate of quality control; or (3) the product is imported from a non-EU Member State with which Italy has entered into an agreement ensuring the quality of medicinal products.

<sup>23</sup> The Circular makes clear that the 1992 Decree also applies to persons that are engaged solely in the export of product, if they keep medicines in warehouses in Italy. The Decree does not apply to traders that do not keep product in warehouses in Italy.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Japan</b></p> <p>Pharmaceutical Affairs Law ("Law"); Enforcement Order of the Pharmaceutical Affairs Law ("Order"); Manufacturing and Quality Control Rules of Drugs and Quasi-Drugs (Ministerial Ordinance No 16 of March 12, 1999) ("GMP Rules").</p> <p>Administered by the Ministry of Health, Labor, and Welfare.</p>	<p>No, MA is not required to <b>import</b>, <u>but</u> must file a notification of products that are imported for export or re-export.</p> <p>Yes, MA is required for products for domestic <b>distribution</b>.</p> <p>No, MA is not required to <b>export</b>, <u>but</u> must file a notification of products that are manufactured for export.</p>	<p>a) Yes. Manufacture and import requires license (Law). The term "manufacturing" is broad and includes packaging.</p> <p>b) Yes. Must comply with certain minimum requirements for products (Law) and the GMP Rules, whether or not product intended for export/re-export.</p>	<p>a) Yes. A distribution license is required for any handling or sale of product, whether or not intended for export.</p>	<p>Yes, must file notification to manufacture/import product for export/re-export.</p>	<p>No. Product is not required to hold a MA.</p> <p>Licensee can import or domestically procure out-of-date products under the notification of (re-)exportation, re-package and export them as new products. This would be unlawful only if the products were "decomposed" or otherwise harmful.</p>	<p>No reported enforcement actions taken against exported product. Regulatory Agency appears less concerned about such products than products for the Japanese market.</p>

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Liechtenstein</b>  Law Governing the Traffic of Medicinal Products within the EEA, and its implementing regulation ("Law").  Administered by the Board of Control for Medicinal Products ( <i>Kontrollstelle für Arzneimittel</i> ).	No, MA is not required to <i>import</i> product.  Yes, MA is required for the <i>supply or marketing</i> of product (Act). <sup>24</sup>  No, MA is not required to import a product for subsequent re- <i>export</i> , as there is no "placing on the market."	a) Yes, manufacturing license is required to "manufacture" <sup>25</sup> a product. Importation of product from non-EEA countries is manufacturing.  b) Yes (Act).	a) Yes, distributors/exporters must hold a license (Act). <sup>26</sup>  b) Yes (Act).	No.  (See footnote 4.)	No. Trans-shipped products are not subject to regulation by the Law, as they are not technically "placed on the market."	Because no laws apply to trans-shipped products, there is no enforcement.  Authorities will inspect for compliance with licensing requirements, as applicable.

<sup>24</sup> The term "placing on the market" is defined as "the placing on the market for the first time by a manufacturer or wholesaler of a medicinal product for which the distribution, the dispensing and the administration must be approved, respectively the first placing on the market of a medicinal product that was approved in accordance with Regulation 2309/93."

<sup>25</sup> The term "manufacturing" is defined as "encompassing the part or full manufacturing, the filling, the packaging, the labeling and the importation [of product] from non-EEA countries" (s30(1) of the Act)

<sup>26</sup> "Wholesaling" encompasses "each activity which consists of purchasing, delivering, exporting of medicinal products with the exemption of the delivering of medicinal products to the public" (s35(1) of the Act).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Luxembourg</b>  Law of August 4, 1975 on Manufacturing and Import ("1975 Law"); Law of April 11, 1983 on Marketing and Advertising of Medicines; Law of January 6, 1995 on Wholesale Distribution of Medicines ("1995 Law"); Grand Duke Decree of September 22, 1992 ("GD Decree").  Administered by the Pharmacy and Medicines Department of the Ministry of Health ("Ministry")	Yes, MA is required to <i>import</i> product (1983 Law).  Yes, MA is required to " <i>place on the market</i> " product. <sup>27</sup>  Yes, MA is required to <i>export</i> product. <sup>28</sup>	a) Yes, authorization is required to manufacture product, whether intended for export or not (1975 Law). Manufacturer's authorization also required to import product from non-EEA countries (1995 Law).  b) Yes (GD Decree). Product imported from outside EU/EEA must be subject to equivalent GMP.	a) Yes, authorization is required for wholesale distribution (1995 Law). Luxembourg authorities recognize manufacturer's authorizations granted in other EU Member States. Those holding manufacturing authorizations are automatically authorized to distribute products.  b) Yes (1995 Law).	No.  (See footnote 4.)	No. Trans-shipped product requires no authorizations if in transit (kept in customs), <b>BUT</b> trans-shipped product that is imported into Luxembourg and then stored for export purposes must be authorized and a wholesaler's or manufacturer's authorization is required (1975 Law).	Trans-shipped product in transit is not regulated, and therefore no enforcement.  The Ministry conducts inspections to ensure permit compliance, where required. However, Ministry admits it does not have resources to enforce pharmaceutical laws as it should.

<sup>27</sup> The term "place on the market" is not expressly defined. However, article 4 of the 1983 Law stresses that "selling, holding for sales, giving for free, or importing medicines" is prohibited unless authorized.

<sup>28</sup> "Wholesale distribution" includes procuring, holding, supplying, or exporting medicines, but does not include delivering medicines to the public (Art. 1 of the 1995 Law).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Netherlands</b>  Medicines Law of 28 July 1958 ("Law"); Decree on the Preparation and Dispensing of Medicinal Products of 8 September 1977 ("Decree").	<p>No, MA is not required to <i>import</i> a product that will be exclusively marketed outside of the Netherlands (Decree).</p> <p>Yes, MA is required to <i>market</i> product in the Netherlands.</p> <p>No, MA is not required for wholesaling for <i>export</i>.</p>	<p>a) Yes, a license is required to manufacture or assemble a product whether intended for export or not (Law and Decree).</p> <p>b) Yes (Decree and rules based on the Decree).</p>	<p>a) Yes, a license is required for "wholesale dealing."<sup>29</sup> A manufacturing license automatically covers sale of the product.</p> <p>b) Yes (Decree).</p>	<p>No, but importation from outside the EU for export requires a license and compliance with GMP &amp; GDP. License covers import and re-export.</p> <p>(See footnote 4.)</p>	<p>No. MA is not required. If trans-shipped products remain under customs controls in the Netherlands, no regulations apply.<sup>30</sup></p>	<p>Because no laws apply to trans-shipped products, there is no enforcement.</p> <p>In general, inspection services are relatively active, and are likely to enforcement against exported products.</p>

<sup>29</sup> "Wholesale dealing" includes any act of selling or supply, or procuring, holding, or exporting a product for the purposes of sale or supply.

<sup>30</sup> One cannot exclude the possibility that regional inspection services could take a different approach.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>New Zealand ("NZ")</b></p> <p>Medicines Act 1981 ("Act"); Medicines Regulations 1984.</p> <p>Administered by MedSafe, a division of the Ministry of Health.</p>	<p>No, MA is not required to <i>import</i> a product.</p> <p>Yes, authorization is required from the Minister of Health to <i>sell, distribute</i> in any way or advertise the availability of a medicine (Act).</p> <p>No, authorization is not required for <i>export</i> of products.<sup>31</sup></p>	<p>a) Yes, a license is required to manufacture a product, whether intended for export or not (Act). The Act does not expressly prohibit export of a product made by an unlicensed manufacturer, but this could be prevented because authorities can seize or demand product if an official reasonably believes an offence has been committed in relation to the product (Act).</p> <p>b) No (unless also distributed in NZ).</p>	<p>a) No. A license is not required to export product that, at the time of export, could lawfully be sold by a pharmacist to a person in NZ.<sup>32</sup></p> <p>b) No.</p>	<p>No.</p> <p>(See footnote 4.)</p>	<p>No. No regulation of trans-shipped products. Products that enter NZ are subject to general quality, safety, and efficacy controls, and authorities could potentially restrict the (re-)export of such medicines.</p>	<p>Trans-shipped products are not regulated, so no enforcement.</p> <p>Enforcement focus for exported products is on activities within NZ, Internet pharmacies, and controlled drugs. Enforcement regarding exports is limited.</p>

<sup>31</sup> An offence will be committed if an exporter undertakes activities in New Zealand such as advertising or distributing prior to export.

<sup>32</sup> Importation, procuring, receiving, storing, use or possession of any prescription medicine requires a license or authorization to manufacture, sell, supply, pack, administer, or possess the medicine and requires that the act be necessary or incidental to the business or purpose for which the person is so licensed or authorized (Act).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/ Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<b>Norway</b>  Act of 4 December 1992 No. 132 relating to medicines etc. ("Act"); Regulation of 22 December 1999 on medicinal products ("1999 Reg"); Regulation of 21 December 1993 on pharmaceutical wholesaling; Regulation of 30 June 1993 on manufacturing and import of medicinal products ("Manufacture Reg").  Administered by the Norwegian Medicines Agency ("Agency").	No, MA is not required prior to <i>import</i> of product.  Yes, MA is required for product to be <i>placed on the market</i> in Norway (Act and 1999 Reg).  Yes, MA is required for product intended only for <i>export</i> .	a) Yes, a license is required to "manufacture" <sup>33</sup> product, even if product intended only for export. (Manufacture Reg).  b) Yes (Manufacture Reg).	a) Yes, a license is required to carry out "wholesaling" <sup>34</sup> business (Act). Those with a manufacturer's or importer's license need not also obtain a wholesaling license.  b) Yes.	No.  (See footnote 4.)	Yes. Trans-shipped products are not exempt from regulations and are subject to relevant license and supervision provisions.	No evidence suggests that inspections or enforcement activities are less rigorous when product is intended only for export.

<sup>33</sup> "Manufacturing" is defined in s1 to includes manufacturing, packing, re-packing, re-labeling, and releasing of medicinal products, and the required testing and control operations in connection with said activities.

<sup>34</sup> "Wholesaling" includes all activities necessary for procurement, warehousing, distribution and export of product, with the exception of distribution to the public.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Portugal</b></p> <p>Decree-Law 72/91 of February 8, 1991 ("Act"); Decree-Law 135/95 of June 9, 1995 on wholesale distribution of medicinal products for human use ("Decree-Law 135/95"); Directorate-General for Customs Guidelines (<i>Circular</i>) No 46/2000 and 55/2000 on import/export of medicines ("Import/Export Guidelines"); Ruling 42/92 of January 23, 1992 on GMP; Ruling 348/98 of June 15, 1998 on GDP ("Ruling 348").</p> <p>Administered by INFARMED, the Portuguese pharmaceutical regulatory agency.</p>	<p>No, MA is not required prior to <i>import</i> (Import/Export Guidelines).</p> <p>Yes, MA or a special authorization is required to <i>market or supply</i> product in Portugal (Act and Decree-Law 135/95).</p> <p>No, MA is not required to <i>export</i> product if exporter has either a Portuguese manufacturing authorization or, for imported products, a certificate of MA or manufacturing authorization from source country.</p>	<p>a) Yes, authorization is required for "manufacture," including any type of manufacturing and operations of division, packaging and layout of product, whether product is intended for export or not.</p> <p>b) Yes (Act and Ruling 42). Where product is imported from outside the EEA, must ensure that manufacturing operations are subject to GMP or its equivalent.</p>	<p>a) Yes, a license is required for either wholesale practice or exportation of product (Decree-Law 135 and Import/Export Guidelines). Those with a manufacturer's or importer's license need not also obtain a wholesaling license.<sup>35</sup></p> <p>b) Yes (Ruling 348).</p>	<p>Yes.</p> <p>INFARMED requires proof of wholesaling license (for export) and one of the documents described in column 2.</p>	<p>No. MA is not required if exporter holds other documents (see column 2).</p>	<p>No evidence to suggest that inspections or enforcement activities are less rigorous when product is intended only for export.</p>

<sup>35</sup> A license is not required if the wholesaler is licensed in another EC member state and does not possess wholesaling facilities in Portugal.

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>South Africa</b></p> <p>Medicines and Related Substances Control Act, No. 101 of 1965 as amended ("Act") and regulations thereunder ("Regs").</p> <p>Administered by the Medicines Control Council ("Council").</p>	<p>No, MA is not required prior to <i>import</i>. Some unregistered grey market goods may be imported (Reg. 7).</p> <p>Yes, MA is required to <i>market or supply</i> product. (Act).</p> <p>No, MA is not required to <i>export</i> product.</p>	<p>a) Yes. No manufacturer, wholesaler, or distributor may manufacture without a license.</p> <p>b) Yes (Act).</p>	<p>a) Yes. No manufacturer, wholesaler, or distributor may import, export, or act as wholesaler or distributor without a license.</p> <p>b) Yes (Act).</p>	<p>No.</p> <p>(See footnote 4.)</p>	<p>No. Trans-shipped products are not subject to any licensing or oversight. Some trans-shipped products may be subject to requirements if the manufacturer, wholesaler, or distributor also supplies product for the domestic market.</p> <p>Trans-shipped product be stored in bonded warehouses registered with the Council and may not be manipulated whilst in these warehouses (Reg 13).</p>	<p>Trans-shipped products are not subject to licensing or oversight. The Council inspects bonded warehouses for compliance in respect of trans-shipments, but relies heavily on the Port or Airport Authorities and Customs to check compliance.</p>

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Spain</b></p> <p>Law 25/1990 on Medicines as amended ("1990 Law"); Royal Decree 767/1993, the evaluation and authorization and registry of medicinal products for human use, as amended; Royal Decree 1564/1992 on the authorization of manufacturers and importers of medicinal products ("1992 Decree"); Royal Decree 2259/1994 on warehouses and the wholesale distribution of medicinal products ("1994 Decree"); Circular 8/2000 provides guidance on the export of pharmaceutical products from Spain ("Circular").</p> <p>Administered by the Spanish Medicines Agency ("SMA"), on behalf of the Ministry of Health ("Ministry").</p>	<p>No, MA is not required to <i>import</i> product. Imported product will require a MA if intended for distribution in Spain (1990 Law).</p> <p>Yes, MA is required for "<i>placing on the market</i>" of product (1990 Law and 1993 Decree).</p> <p>No, MA is not required for <i>export</i> of products (as they are not placed on the market) <u>but</u> notification may be required (see column 5).</p>	<p>a) Yes, authorization is required to manufacture product, whether intended for export or not (1990 Law, 1992 Decree, and Circular).</p> <p>b) Yes, whether product is intended for export or not. Where product is imported from outside the EU/EEA, must ensure that manufacturing operations are subject to GMP, at least equivalent to those applicable in EU (1992 Decree).</p>	<p>a) Yes, authorization is required for warehousing, distribution and export of product (not required for authorized manufacturers) (1990 Law and 1994 Decree).</p> <p>b) Yes (1994 Decree).</p>	<p>Yes.</p> <p>Products must be notified to the Ministry if subject to a MA in Spain, or authorized by the Ministry, if not subject to a MA in Spain (1990 Law and Circular).</p>	<p>No. MA is not required. However, licensing and notification/authorization requirements apply.</p>	<p>SMA has discussed export issues, but extent of enforcement is unclear.</p>

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Sweden</b></p> <p>Pharmaceutical Act (1992:859) ("Act"); Trades of Pharmaceuticals Act (1996:1152); MPA's Provisions on Authorization for the Manufacturing of Medicinal Products (LVFS 1995:3) ("Manufacturing Provisions"); MPA's Provisions on Authorization for the Wholesale trade of Medicinal Products (LVFS 1997:3) ("Wholesale Provisions").</p> <p>Administered by the Medicinal Products Agency ("MPA").</p>	<p>No, MA is not required prior to <i>import</i> of product.</p> <p><b>Yes</b>, MA is required for the <i>sale and marketing</i> of product (Act).</p> <p>No, MA is not required prior to <i>export</i> of product.</p>	<p>a) <b>Yes</b>, a manufacturer's authorization is required to "manufacture" product (includes "preparation, packaging and re-packaging") whether intended for export or not (Act).</p> <p>b) <b>Yes</b> (Manufacturing Provisions). Product imported from outside EEA must be manufactured according to GMP.</p>	<p>a) <b>Yes</b>, a wholesale trade authorization is required to "wholesale trade" products, including "all activities that encompass acquisition, possession, export and distribution of medicinal products."</p> <p>b) <b>Yes</b> (Wholesale Provisions).</p>	<p><b>No</b>.</p> <p>Import authorization is required if importer acts only as import agent for products from outside the EEA.</p> <p>(See footnote 4.)</p>	<p><b>No</b>. A MA is not required. However, wholesale trade authorization or manufacturer's authorization is required to import, and must comply with GDP. Also subject to MPA surveillance.</p>	<p>No evidence suggests that inspections or enforcement activities are less rigorous when product is intended only for export.</p>

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/ Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>Switzerland</b></p> <p>Federal law on Medicinal Products and Medical Devices, <i>Heilmittelgesetz</i> ("HMG"); Regulation on Licenses in the Medical Field, <i>Arzneimittel-Bewilligungsverordnung</i> ("AMBV"); Swissmedic Fact Sheet on Importation of Medicinal Products (Jan. 2003) ("Factsheet").</p> <p>Administered by Swissmedic.</p>	<p>Yes, MA is required to <i>import</i> finished product unless product is not subject to MA requirement (HMG and Factsheet).<sup>36</sup></p> <p>Yes, MA is required for "<i>placing on the market</i>" product (defined as "the distribution and the supply of therapeutic products").</p> <p>No, MA is not required to <i>export</i> product. Product may not be exported if (i) it is prohibited in the destination country; or (ii) there is any suggestion that it is intended for illegal purposes (HMG).</p>	<p>a) Yes, a manufacturer's license is required to manufacture a product, whether intended for export or not.<sup>37</sup></p> <p>b) Yes (AMBV).</p>	<p>a) Yes, wholesalers must be licensed.</p> <p>b) Yes (Factsheet).</p>	<p>Yes, an export license is required for export of finished products (HMG).</p> <p>(See footnote 4.)</p>	<p>No. No license is required to trans-ship products. However, storage of product in a customs warehouse is importation, and the requirements for importing medicines apply and MA is required.</p>	<p>No evidence suggests that inspections or enforcement activities are less rigorous when product is intended only for export.</p>

<sup>36</sup> Pursuant to Article 9 of the HMG, galenic preparations, investigational products, and customized products are not subject to a marketing authorization. Imports for personal use and imports by medical professionals also are exempt from the MA requirement. Any other imported products must be covered by a valid Swiss marketing authorization.

<sup>37</sup> "Manufacture" is defined to include "all stages of manufacture of therapeutic products, from the acquisition of the starting materials through the processing to the packaging, storage and delivery of the final products, as well as the quality controls and batch release" (Art. 4(1)(c) of the HMG).

1. Country and Applicable Laws/Regulations	2. Marketing Authorization ("MA") or license required for import, supply or export?	3(a) Manufacturer's Authorization for exported product?  (b) Compliance with GMP?	4(a) Distribution/Wholesaler's Authorization for exported product?  (b) Compliance with GDP?	5. Exports Notified/Approved?	6. Products imported solely for export ( <i>trans-shipped products</i> ) regulated as strictly as products imported for domestic sale?	7. Enforcement of rules for exported product?
<p><b>UK</b></p> <p>Medicines for Human Use (Marketing Authorizations, Etc.) Regulations 1994 (S.I. 1994/3144) ("1994 Regs"); Medicines Act 1968 ("Act"); Medicines (Standard Provisions for Licenses and Certificates) Regulations 1971 ("1971 Regs"); Medicines (Exemption from Licenses) (Wholesale Dealing) Order 1990 (SI 1990 No 566) ("1990 Order").</p> <p>Administered by the Medicines and Healthcare Products Regulatory Agency ("MHRA").</p>	<p>No, MA is not required to <i>import</i> product.</p> <p>Yes, MA is required to <i>supply or market</i> product in the UK (1994 Regs).<sup>38</sup></p> <p>No, MA is not required to <i>export</i> product.</p>	<p>a) Yes, a license is required to manufacture or assemble a product, whether intended for export or not (Act).<sup>39</sup> Importation of product from outside the EEA is manufacturing and requires a wholesale dealer's import license (Act).</p> <p>b) Yes (1971 Regs). Product imported from outside EEA must be subject to at least equivalent GMP.</p>	<p>a) Yes, wholesale dealing license is required to distribute by wholesale (Act)<sup>40</sup> <b>but</b> importers who do not own products and act solely as a transporter for products from outside the EEA, do not require a license (1990 Order). No license required to export products direct to countries outside the EEA.</p> <p>b) Yes (1971 Regs).</p>	<p>No.</p> <p>(See footnote 4.)</p>	<p>No. Trans-shipped products are not regulated unless they are subject to a manufacturing operation, for which a manufacturer's license will be required.</p> <p>Wholesale dealer and import licenses are not required for trans-shipped products.</p>	<p>Trans-shipped products are not regulated, and no enforcement activities are conducted.</p>

<sup>38</sup> Marketing or distributing a product by way of wholesale dealing requires a MA. The term "wholesale dealing" encompasses the sale of a medicinal product in the course of a business, to a person who buys it for sale or supply, or for administration to a human being. The term "place on the market" is not defined but it is generally understood to involve transfer of product to a third party.

<sup>39</sup> Section 132 of the Medicines Act 1968 defines the term "manufacture" to include "any process carried out in the course of making the product" and "assemble" as "enclosing the product (with or without other medicinal products of the same description) in a container which is labeled before the product is sold or supplied, or, where the product is already enclosed in the container in which it is to be sold or supplied, labeling the container before the product is sold or supplied in it." "Manufacture" includes testing and may include "assembly."

<sup>40</sup> Wholesale distribution includes any act of selling or supply, or procuring, holding or exporting a product for the purposes of sale or supply.

## Appendix

### Table of Contents

Australia.....	2
Austria.....	5
Belgium.....	9
Canada.....	13
Denmark.....	19
Finland .....	22
France .....	24
Germany.....	29
Greece .....	32
Iceland.....	36
Ireland .....	39
Israel .....	42
Italy .....	46
Japan .....	49
Liechtenstein.....	52
Luxembourg.....	55
Netherlands .....	58
New Zealand.....	61
Norway.....	65
Portugal.....	68
South Africa.....	72
Spain .....	75
Sweden.....	78
Switzerland .....	81
UK .....	84

**Australia**

*Bernard O'Shea*

*Deacons*

*Tel: +61 (0)3 8686 6573*

*Email: [bernard.oshea@deacons.com.au](mailto:bernard.oshea@deacons.com.au)*

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The federal Therapeutic Goods Act 1989 ("the TG Act")<sup>1</sup> and the Therapeutic Goods Regulations 1990 ("the TG Regs")<sup>2</sup> (together, "the TG Legislation") regulate all relevant aspects of medicines in Australia. Medicines are required to be registered or listed on the Australian Register of Therapeutic Goods ("ARTG"), whether they are to be supplied in Australia or exported from Australia. Under section 20 of the TG Act, it is an offence to import medicines into Australia, export medicines out of Australia, or manufacture or supply medicines in Australia, if the medicines are not either registered or listed on the ARTG, exempt under the TG Legislation from the requirement to be registered or listed, or approved or authorized under the TG Legislation.

The TG legislation is administered by the Therapeutic Goods Administration ("TGA"). Its duties include approving registrations or listings and issuing appropriate licenses to importers, manufacturers, distributors and exporters of medicines.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

The marketing authorization is the approval or authorization to supply a medicine in Australia. It is granted by the TGA to the "sponsor" of the medicine. "Sponsor" is defined in the TG Act as the person who exports medicines out of or imports medicines into Australia, or who manufactures medicines in Australia. The definition excludes a person who undertakes these activities on behalf of a person who is a resident of Australia or who is carrying on business in Australia (in which case that person would be the sponsor).

Medicines that are intended solely for export do not require a marketing authorization, but are accepted for listing on the ARTG, subject to their compliance with basic quality and safety criteria. This applies to export only medicines which are imported into, or,

---

<sup>1</sup> <http://scaleplus.law.gov.au/html/pasteact/0/400/top.htm>.

<sup>2</sup> <http://scaleplus.law.gov.au/html/pastereg/0/25/top.htm>.

which are manufactured in Australia. Section 28 of the TG Act allows the TGA to impose conditions on the registration or listing of medicines on the ARTG. For instance, the TGA could require the goods to be manufactured for “export only.” Medicines which are to be supplied in Australia (whether they are manufactured in Australia or imported) must obtain a marketing authorization from the TGA.

**(b) must manufacturers of such products hold a manufacturer’s authorization?**

Section 35 of the TG Act makes it an offence for a person to carry out any step in the manufacture of medicines unless they are licensed by the TGA. The term “manufacture” is defined in the TG Act to mean production of medicines, or engaging in any part of the process of producing the medicines to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the medicines or of any component or ingredient of the medicines as part of that process. This requirement applies to all medicines manufactured in Australia, whether intended for supply domestically or for export.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Under section 36 of the TG Act, manufacturing principles (which may change from time to time) must be observed in the manufacture of medicines. To obtain a license to manufacture medicines, a manufacturer must therefore demonstrate, during a factory audit, compliance with manufacturing principles which includes relevant Australian Codes of GMP.

A sponsor applying to the TGA for registration or listing of a medicine manufactured outside Australia must provide an acceptable form of evidence showing that the manufacture is of an acceptable standard, referred to as “GMP clearance of overseas manufacturers.” This requirement applies even when the medicines are intended solely for export.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

A person is only able to export medicines if the goods are listed goods in relation to that person. In other words, the person must be the sponsor of the goods and must have fulfilled all requirements for listing on the ARTG.

The TG Legislation does not explicitly require distributors to hold a license. However, storage and distribution of products, other than fully finished medicines, may fall within the definition of “manufacture” (see above) and so may require a license under section 35 of the TG Act.

Further, State legislation generally requires a person who supplies medicines “by wholesale” to hold a license to supply by wholesale. An exhaustive survey of all State legislation is outside the scope of this document. However, we note that the States’ treatment of medicines, particularly prescription medicines, is consistent. In the

Victorian Therapeutic Goods Act 1994, "supply by wholesale" is defined to mean supply for the purposes of resale. Australian wholesalers are required to demonstrate appropriate storage, handling and supply practices and are further required to comply with the TGA's Code for Good Wholesaling Practice.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no pre-notification or pre-approval requirements that must be fulfilled prior to the export of medicinal products.

The TGA will issue Certificates of Pharmaceutical Product to exporters on request, to assist in satisfying import requirements in other countries. However, there is no requirement in law for this.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

This ultimately depends on whether the TGA takes the view that trans-shipment involves import into and/or export out of Australia. Clearly, to be unregulated, trans-shipment must involve no aspect of "manufacture" as referred to above. The current view is that provided trans-shipment is part of a continuous carriage within the control of a single person and the goods never clear customs, it would not be treated as an import or export.

**5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

The TGA will actively enforce its rules when it becomes aware of any breaches. In particular, it will enforce if it becomes aware of non-sponsors exporting products. The extent of any active audit program by them is unknown. It is likely that they rely on the Customs authorities to identify potential breaches or risk areas. They will also act on information from sponsors.

**Austria**

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The manufacturing, importation, placing on the market, and the exportation of medicinal products is primarily regulated by the Medicines Law (*Arzneimittelgesetz*, or “AMG”), by the Law on the Importation of Medicinal Products (*Arzneiwareneinfuhrgesetz*), and by further implementing regulations.

The Ministry of Health and Women grants marketing authorizations for medicinal products, importation licenses, manufacturer licenses and licenses for placing the product on the market. The Ministry of Health and Women is also responsible for conducting the relevant inspections.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to section 11 of the AMG, no medicinal product can be placed on the market without a valid marketing authorization. The term “placing on the market” is defined as “the storage, the keeping available or the delivery of medicinal products.” However, products are not considered to be placed on the market if they are stored in such a way as to guarantee that no final consumer or user has access to the products (section 2(11) of the AMG). As a result, products intended for exportation, and stored separately from other products, do not require a marketing authorization.

Pursuant to the Law on Importation of Medicinal Products, medicinal products may not be imported into Austria without a prior authorization from, or notification to, the Ministry of Health and Women Products. The law covers the products contained in Custom Headings 3004, (including medicines packaged for retail sale)<sup>1</sup> 3006 30,<sup>2</sup> 3006 60,<sup>3</sup> and covers placentas under heading 3001 90.

---

<sup>1</sup> This provision covers medicaments (excluding goods included in heading 3002, 3005, or 3006) either consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (including trans-dermal administration systems), or in forms or packaging for retail sale.

<sup>2</sup> This provision covers opacifying preparations for X-ray examinations and diagnostic reagents to be administered to patients.

<sup>3</sup> This provision covers chemical contraceptive preparations based on hormones, other products contained in heading 2937, or spermicides.

The import of products authorized in an EEA country need only be notified to the Ministry of Health and Women Products. Import of products from a non-EEA country must be authorized. Pharmacists, marketing authorization holders, and wholesalers apply to the Ministry of Health and Women Products to obtain an authorization to import medicines. The application must include the quantities of products to be imported, product information, and the purpose of the import.

An importation license may only be granted for the import of the following products:

- (i) products that are intended for export;
- (ii) products that are imported for scientific purposes and are not intended for administration to humans and animals; and
- (iii) products that are intended for administration to humans or animals and are imported for therapeutic or scientific purposes. This category includes investigational products and so-called "compassionate use" products.

**(b) must manufacturers of such products hold a manufacturer's authorization?**

Section 63 (1) of the AMG requires any person manufacturing<sup>4</sup> medicinal products to obtain a license from the Ministry of Health and Women. A license will be granted if (i) the applicant complies with the provisions contained in the Regulation Applicable to Manufacturers, Depositors<sup>5</sup> and Wholesalers (*Verordnung betreffend die Betriebe der Arzneimittelhersteller, Deposituere und Arzneimittel-Großhändler*) and (ii) the facility is equipped in such a way as to guarantee product quality.

The Ministry of Health and Women will only issue a manufacturer's license when it is satisfied that the information contained in the application is accurate and complies with the legislative requirements. The Ministry usually inspects the site before issuing the license.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Holders of a manufacturing license must comply with the requirements set out in the Regulation Applicable to Manufacturers, Depositors and Wholesalers, which implements the European principles of GMP.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

---

<sup>4</sup> "Manufacturing" is defined as "the extracting, the producing, the preparing, the finishing, the processing, the transfer in other containers, bottles, etc., and the packaging of medicinal products as well as the labeling."

<sup>5</sup> The term "depositors" encompasses pharmacists importing medicinal products that are produced in a third country.

Persons placing medicinal products on the market (by storing, delivering, or keeping at disposal) must obtain an appropriate license from the Ministry of Health and Women, under section 63(1) of the AMG. In addition, the wholesale distribution of medicinal products is regulated as a restricted trade (*gebundenes Gewerbe*) and persons engaging in it must also comply with the requirements of the Industrial Code (*Gewerbeordnung*). Wholesalers must comply with the Regulation Applicable to Manufacturers, Depositors and Wholesalers, which implements the principles of good distribution practice ("GDP").

No license is required to export medicinal products because section 63(1) covers only the manufacturing, control, and the placing on the market of medicinal products. Also, products can be exported without a marketing authorization, provided that the products are stored separately from authorized products and in such a way as to guarantee that the final user (e.g., the patient or physician) has no access to the products (see section 1, above, regarding the definition of "placing on the market").

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

The Austrian government imposes no pre-notification or pre-approval requirements for the export of medicinal products other than products containing a narcotic, psychotropic or other controlled substance. The Ministry of Health and Women will issue export certificates on request to assist exporters in satisfying import requirements in other countries.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Trans-shipped products are not covered by the AMG or by the Law on the Importation of Medicinal Products. The latter specifically states that trans-shipping (*Durchfuhr*) is not considered as importation and import approval by the Ministry of Health and Women is therefore not required. Further, the AMG should not be applicable because such products are not placed on the market.

**5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

Because trans-shipments are not subject to the laws, no enforcement is necessary with regard to these products.

To the extent that an Austrian manufacturer's or wholesale dealer's license is required, the regional authorities will conduct inspections on behalf of the Ministry of Health prior to the grant of the license and on a regular and repeated basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their licenses, with Austrian law, and with European GMP or GDP as appropriate. There is no

**COVINGTON & BURLING**

evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Belgium

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines Law of 17 April 1964 ("the Law" - *Wet op de Geneesmiddelen*) and the Decree on the Manufacturing, Distribution and Supply of Medicines of 6 June 1960 ("the Decree" - *Koninklijk Besluit betreffende de fabricage en distributie in het groot en de terhandestelling van geneesmiddelen*) provide the legislative basis for control of medicinal products through a system of licenses and authorizations. Amongst other things, they make it unlawful to market, manufacture, distribute, sell, or supply medicinal products in Belgium and to import and export medicinal products to or from Belgium, except with appropriate approvals.

The DG Public Health Protection: Medicinal Products (formerly called the Pharmaceutical Inspection) monitors the implementation of the Law.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

A marketing authorization is not required if medicinal products are not intended to be marketed in Belgium. According to an official, a drug is not placed on the market if it is merely sold at wholesale for export purposes. However, a declaration for each medicinal product is required in order to manufacture and to import for export purposes (see 2(b) below).

- (b) **must manufacturers of such products hold a manufacturer's authorization?**

Article 2 of the Decree requires any person who manufactures or assembles a medicinal product to hold a license from the competent Minister. This obligation applies even if the medicinal product is intended only for export.

Applicants for manufacturing licenses must provide detailed information on the production and/or control of the relevant pharmaceutical manufacturing operations.

For unregistered products that are intended for export, the manufacturer also must supply additional product information. This so-called "declaration" is, in effect, a simplified registration procedure. The declaration must include the complete qualitative and quantitative composition and a complete chemical-pharmaceutical dossier.

- (c) **must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

The Decree requires that all manufacturing license holders conduct all manufacture and assembly operations in accordance with European GMP. The Decree expressly provides that medicines manufactured in Belgium and intended for export are subject to the same requirements as medicines intended for the Belgian market and need to comply with the registration dossier, or, if not available, with the defined or approved specifications of the destination country.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Article 2 of the Decree requires that any person distributing or exporting medicinal products obtain a license from the competent Minister.<sup>1</sup> The license holder must comply with the good distribution practices, implemented by the Ministerial Decree of 17 October 1995.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

There are no Belgian government pre-notification or pre-approval requirements for the export of medicinal products, although specific rules govern certain substances, e.g., products containing a narcotic, psychotropic, or other controlled substance. Otherwise, the exporter need only obtain a general exporting license. Upon request by the manufacturer, the destination country, or the exporter, the inspection services will confirm that a particular manufacturer possesses the necessary licenses.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

An importation and exportation license is required to import finished medicinal products from outside the EU for re-exportation outside the EU. The license holder must comply with all of the Decree's requirements, including Good Distribution Practices. In addition, if the exported products do not have a Belgian or European marketing authorization, the exporter must declare the medicines to the inspection services (as discussed in 2(b) above).

A less restrictive regime applies to those products imported only for export, if:

- (i) the medicines are being exported without any further processing or handling within Belgium;

---

<sup>1</sup> A manufacturer is entitled to sell products under the manufacturing license. However, a separate license is required to export the products.

- (ii) the medicinal products clearly indicate the person responsible for the marketing of the products in the destination country and, if different, the manufacturer; and
- (iii) there is no reference to any person established in Belgium.

If the above conditions are met, the following rules apply:

- (i) A chemical-pharmaceutical dossier (normally part of the declaration) and batch release are not required;<sup>2</sup>
- (ii) Each product must be accompanied by a batch release certificate signed by the qualified person within the manufacturer. This certificate must ensure conformity with GMP and the relevant specifications. It must contain the results of the tests on the raw materials and the finished product, including a complete quantitative and qualitative analysis of all active substances, as well as all examinations necessary to ensure the quality of the medicine; and
- (iii) The exporter obtain the following documents from the government of the country of origin and make them available to the inspection services upon request:
  - (A) a certificate confirming that the manufacturer possesses the necessary licenses and meets the GMP standards of the World Health Organization in product manufacture and control;
  - (B) a certificate describing the qualifications of the manufacturer's qualified person ; and
  - (C) a sample of the qualified person's official signature.

The exporter must possess these documents for each manufacturer of imported products and must have the documents available at the first importation and at each subsequent change.

A governmental official informs us that the situation is unclear when products remain under customs control in Belgium. In practice the inspection services do not have access to such products and thus cannot inspect the products.

---

<sup>2</sup> If the conditions discussed above are not met, the inspection services will expect a batch release to be performed in Belgium, although exemptions and a less restrictive regime are possible under an agreement between the EU and a third country. Furthermore, this batch release is not clearly required if the products will not be released on the Belgian market.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

We are not aware to what extent the Belgian inspection services enforce the rules regarding products intended only for export. In general, there are regular inspections but the intensity depends on the general workload and specific circumstances on the market. It is possible that businesses focusing on import-export activities are subject to less vigorous controls.

## Canada

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Food and Drugs Act, R.S.C. (1985), c. F-27, as amended (“the Act”) and the Food and Drug Regulations, C.R.C., c. 870, as amended (“the Regulations”) constitute the legislative basis for the regulation of drugs in Canada. Drugs fabricated or imported for sale in Canada require a marketing authorization prior to sale. Unless drugs are fabricated for export and are not sold in Canada, those engaged in the fabrication, packaging, labeling, distribution, importation or wholesaling of a drug require an establishment license.

The Health Products and Food Branch (“HPFB”) of Health Canada regulates drugs by, *inter alia*, the review of applications for marketing authorizations and establishment licenses. The HPFB Inspectorate conducts inspections to ensure compliance with, *inter alia*, the terms of establishment licenses and Canadian GMP requirements.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

The general scheme established by the Act and Regulations prohibits the sale of any drug products unless the transaction falls within one of the listed exceptions. Section 2 of the Act defines “sell” to include “offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.”

The most commonly applied exception is one that permits sales of a drug for which the relevant Minister has issued a Notice of Compliance (“NOC”),<sup>1</sup> upon the presentation of a valid prescription by a patient to a pharmacist. However, paragraph C.01.043 of the Regulations also permits the sale of prescription drugs without the presentation of a valid prescription to drug manufacturers, practitioners, drug wholesalers, registered pharmacists, hospitals certified by the Department of National Health and Welfare and to the Canadian Government.

**Import** -- The Regulations state that “no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.”<sup>2</sup> Health Canada interprets this, in conjunction with the broad definition of

---

<sup>1</sup> An NOC is the Canadian equivalent of a marketing approval or U.S. NDA. NOCs are issued pursuant to Regulation C.08.004(1)(a).

<sup>2</sup> Regulation A.01.040.

the term "sell" under the Act, to require that all imported products must comply with all requirements of the Act and the Regulations, whether or not they are intended for re-export.

**Export** -- There is no provision in the Act or Regulations that expressly permits or prohibits the export of drug products that have been imported, manufactured, or sold for the Canadian market, nor does the export of Canadian drug products fall within any of the listed exceptions to the general prohibition on the sale of drug products under the Act. Taken together with provincial legislation governing pharmacies, this could be interpreted to preclude the retail sale of drug products to patients outside Canada without a valid Canadian prescription. However, Health Canada interprets regulation C.01.043 to allow Canadian drug manufacturers and wholesalers to sell Canadian drug products to United States wholesalers, without the need for a valid prescription or any form of government pre-approval.<sup>3</sup>

Different rules apply if a drug product is not manufactured for consumption in Canada and not sold for consumption in Canada. According to section 37, the Act does not apply if the exporter notifies the Health Canada's Health Products and Food Branch Inspectorate (the "Inspectorate") of the relevant drug products and signs an export certificate<sup>4</sup> indicating that:

1. the drug products are labeled for "Export";
2. the drug products being exported were not manufactured for consumption in Canada and are not sold for consumption in Canada; and
3. the drug products do not contravene any known requirement of the law of the country to which it is or is about to be consigned.

Section 37(1) represents an exception, not only to the general prohibition against sales, but to the Act as a whole, including the requirement for pre-market approval and the controls on manufacturing and distribution. Where the exemption applies, Health Canada's sole concern would be to ensure that the preconditions to invoking the exemption are satisfied. Products that benefit from this exemption are not subject to any other form of regulatory oversight or control. They will not be inspected by the Inspectorate for compliance with GMP requirements and Health Canada plays no role in controlling their efficacy, safety or quality.

The section 37 exemption does not apply to drugs that are imported, produced, or sold, for the Canadian market. Any products imported or manufactured for, and intended to be

---

<sup>3</sup> Regulation C.01.043 also permits the sale of Canadian product to certain practitioners, pharmacists and hospitals. However, the term "practitioner" is defined as a person licensed to practice medicine in Canada and registered pharmacists and certified hospitals are arguably also restricted to Canada.

<sup>4</sup> Regulation A.01.045 and Appendix III of the Regulations set out the form of the required Section 37 certificate. The exemption does not apply to the controlled and restricted drugs listed in appendices to the Act. The exemption would also not apply if an exporter does not formally notify the Inspectorate of its intention to invoke section 37, has not executed the appropriate certificate, or has failed to identify the product as being for "export."

sold to, the Canadian market must have an NOC and will be treated as being for consumption in Canada, irrespective of whether a Canadian manufacturer or distributor subsequently wishes to export them. A section 37(1) export certificate is therefore an inappropriate basis for the export of a drug product where an NOC is in effect for the product, the product complies with the NOC and general provisions of law on the labeling and composition of drugs, and there is no other violation of the Act.

The section 37(1) exemption would be available if Canadian product was repackaged<sup>5</sup> or relabeled for the purpose of export, since it would no longer be manufactured for consumption in Canada. Provided the entity identifies the products as being for export, signs an export certificate and notifies the Inspectorate of the products concerned, the activities of any Canadian entity packaging or labeling Canadian product for the United States market would fall outside Health Canada's jurisdiction. There would then be no regulatory control over the product's safety, quality and efficacy, or the manner in which the products are stored, handled or distributed prior to their export to the United States.

**(b) must manufacturers of such products hold a manufacturer's authorization?**

Canada imposes a system of pre-market approval for new drugs, and a new drug submission ("NDS") is required to contain detailed information on manufacturing facilities and methods. In addition, regulation C.01A.004 prohibits the fabrication,<sup>6</sup> packaging/labeling,<sup>7</sup> distribution,<sup>8</sup> import<sup>9</sup> or wholesale<sup>10</sup> of a drug<sup>11</sup> except in accordance with an establishment license. The holders of such licenses are referred to as drug establishments.

Fabricators of drugs intended for export who have invoked the section 37 exemption are not required to hold establishment licenses or to comply with Canadian GMP

---

<sup>5</sup> The term "repackage" in this context entails a degree of manipulation of a drug product's primary or secondary packaging. The mere act of packaging finished, packaged and labeled Canadian drug products into receptacles for shipping purposes does not constitute repackaging or fabrication for these purposes.

<sup>6</sup> To "fabricate" (manufacture) means to prepare and preserve a drug for the purposes of sale.

<sup>7</sup> To "package/label" means to put a drug in its immediate container or to affix the inner or outer label to the drug.

<sup>8</sup> Regulation A.01.010. defines the term "distributor" as a "person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug."

<sup>9</sup> To "import" means to import into Canada a drug for the purpose of sale.

<sup>10</sup> To "wholesale" means to sell any of the following drugs, other than at retail sale, where the seller's name does not appear on the label of the drugs:

(a) a drug listed in Schedule C (radiopharmaceuticals) or D to the Act or in Schedule F to these Regulations or a controlled drug as defined in subsection G.01.001(1); or

(b) a narcotic as defined in the Narcotic Control Regulations.

<sup>11</sup> In this context, the term "drug" includes pharmaceuticals, vaccines, whole blood and its components, drugs listed in Schedule D to the Act (biologics), other than vaccines or whole blood and its components, drugs listed in Schedule C to the Act (radiopharmaceuticals), drugs listed in Schedule F to the Regulations, controlled drugs and narcotics.

requirements in respect of those products. Neither their facilities nor the relevant products will be inspected by the Inspectorate for compliance with GMP requirements. There is therefore no regulatory control over the quality or safety of the products, or the manner in which they are handled, stored or distributed prior to their export to the United States. The Inspectorate's sole concern will be to ensure compliance with the preconditions to that exemption.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

All drug establishments involved in the fabrication, packaging, labeling, testing, distribution, importation and wholesaling of drugs must comply with Division 2 of the Regulations (the "GMP Regulations").<sup>12</sup> These require that they establish and maintain suitable premises,<sup>13</sup> equipment,<sup>14</sup> personnel,<sup>15</sup> and quality control/batch release procedures.<sup>16</sup> There are also associated sample<sup>17</sup> and record-keeping<sup>18</sup> obligations.

Fabricators of drugs intended for export who have invoked section 37 of the Act are not required to comply with Canadian GMP requirements in respect of those products. Such products will not be inspected by the HPFB Inspectorate for compliance with GMP requirements.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

N/A (see above).

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Fabricators must notify HPFB of those drug products for which they are invoking the section 37 exemption. No prior approval by HPFB is required as long as all of the preconditions to the exemption are satisfied.

The HPFB Inspectorate will, upon request, issue a WHO Certificate of a Pharmaceutical

---

<sup>12</sup> Regulation C.02.003 provides that no distributor or importer shall sell a drug unless it has been fabricated, packaged/labeled, tested and stored in accordance with the GMP Regulations. This requirement that products be manufactured in accordance with GMP also applies to foreign drug establishments providing drugs to the Canadian market.

<sup>13</sup> Regulation C.02.004.

<sup>14</sup> Regulation C.02.005.

<sup>15</sup> Regulation C.02.006.

<sup>16</sup> Regulations C.02.013 and C.02.014.

<sup>17</sup> Regulations C.02.025 and C.02.026.

<sup>18</sup> Regulations C.02.020 to C.02.024.

Product certifying whether the drug to be exported is marketed in Canada and complies with Canadian GMP. This is to satisfy the requirements of the importing country and is not a Canadian export requirement.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Canadian legislation does not recognize the concept of trans-shipment. Products imported into Canada must be subject to an NOC and those importing or distributing the product must hold an establishment license and comply with Canadian GMP Regulations, unless the section 37 exemption is invoked. This exemption may be invoked in respect of products that have been relabeled or repackaged for the United States market, and Canadian rules ensuring the safety, quality, and efficacy of drug products are disappplied. Health Canada does not regulate these products. In any event, Health Canada takes the position that it cannot guarantee the safety, quality or efficacy of any Canadian product exported to the United States.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

Unless the section 37 exemption is invoked, Canadian importers, manufacturers, packagers, labelers and distributors of products sold in Canada for the Canadian market are subject to the applicable requirements of the Act and Regulations until the products are consigned for export from Canada. They must hold establishment licenses and comply with the GMP Regulations. A strict application of Canadian law suggests that its application should be identical for all imported products whether they are subsequently intended for export or for domestic consumption. However, Health Canada's stated position is that it has no jurisdiction or power to regulate export sales or to guarantee the safety or quality of exported products.

According to an official within the Inspectorate with whom we talked on an informal basis, Health Canada's role is to ensure the quality and safety of product on the Canadian market that might be sold for consumption in Canada. It cannot guarantee the safety, quality or efficacy of exported products. The regulatory scheme established by the Act and Regulations focuses on product sales, and the Inspectorate's position is that export sales take place in another country. Such sales therefore fall outside both Health Canada's mandate and its jurisdiction. Ensuring the safety, efficacy and quality of the products concerned is a matter for the drug regulator in the destination country.

The official indicated that, in practice, Health Canada does not regulate entities that engage solely in the export of products from Canada. For entities that are involved in both the sale of products for the Canadian market and their export, the official felt that the obligation to hold establishment licenses and to comply with the GMP Regulations applies only to activities involving products intended for Canadian consumers.

The official applied a similar rationale to the re-export of imported products. Health

Canada would not actively regulate the activities of entities that engage solely in the import of products for re-export, where products were not intended to be sold to the Canadian market. Moreover, the section 37 exemption may be invoked in respect of products that have been relabeled or repackaged for the United States market, and Canadian rules ensuring the safety, quality and efficacy of drug products are disappplied. Health Canada does not regulate these products. In any event, Health Canada takes the position that it cannot guarantee the safety, quality or efficacy of any Canadian product exported to the United States.

**Denmark**

*Poul Heidmann*

*Jonas Bruun*

*Tel: +33 47 88 73*

*Email: PHE@jblaw.dk*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

Section 8(1) of the Medicinal Products Act states that companies may only produce, import, export, store, market, dispense, distribute or pack pharmaceutical products, subject to relevant approvals the Danish Medicines Agency. Section 8 forms the basis of the authorities' regulation of individual companies and the control of their subsequent handling of products. Section 9(1) of the Medicinal Products Act allows the Danish Medicines Agency to inspect entities that hold such approvals.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

Marketing authorizations are not required prior to the mere act of importing or exporting medicinal products into or from Denmark. However, a marketing authorization is required in order to place a product on the Danish market.

According to section 9(5) of the Medicinal Products Act, holders of authorizations for manufacture and export of medicinal products must, on request, provide the Danish Medicines Agency with the reasons for not having applied for marketing authorization for a medicinal product.

- (b) must manufacturers of such products hold a manufacturer's authorization?**

Manufacturers of medicinal products intended only for export must hold a manufacturer's authorization. Under section 8(1) of the Medicinal Products Act, medicinal products must not be manufactured or packed without an authorization from the Danish Medicines Agency.

Import to Denmark from third party countries (i.e. non-EEA countries) requires an authorization similar to a manufacturing authorization. Holders of manufacturing authorizations are also entitled to store and distribute medicinal products.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Holders of a manufacturing license must comply with the requirements set out in the Executive Order on Good Manufacturing (GMP) and Good Distribution (GDP) Practice for Medicinal Products (EO No. 264 of 4 April 1997) ("the GMP and GDP Order").

Section 1(2) of the GMP and GDP Order specifically states that the Order regulates the import and manufacture of medicinal products, including manufacture for export.

Part 4 of the GMP and GDP Order requires that importers of products from outside the EEA must employ a qualified person responsible for ensuring and certifying that every batch of an approved pharmaceutical specialty was manufactured in accordance with European GMP and fulfills the requirements of the marketing authorizations. Such control must take place in Denmark and comprise a complete qualitative and quantitative analysis of all active components, as well as any other test/control required to ensure the quality of the medicinal product.

The regulations are optional (non-mandatory) if appropriate and equivalent control certificates are available from other countries.

Similar, but less detailed, regulations apply to import of medicinal products from EEA countries.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

A wholesale distribution/trade authorization is required to import medicinal products from within the EEA and for subsequent wholesale trade.. In addition to permitting wholesale trade, such distributor/dealer authorizations also allow the storage and export of medicinal products.

Holders of a distributor/dealer authorization must comply with the requirements set out in the GMP and GDP Order, including compliance with good distribution practices.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless a product contains a narcotic, psychotropic or other controlled substance, there are no Danish government pre-notification or pre-approval requirements that must be fulfilled prior to export of medicinal products.

The Danish Medicines Agency has established an export register, in which medicinal products intended for export can be listed voluntarily. The regulations are laid down in the Ministry for the Interior and Health's Circular no. 14 of 29 January 1998.

The Danish Medicines Agency exercises a degree of control over companies whose products have been listed in the export register, and impose requirements for product

components, quality, storage, and manufacturing. The Medicines Agency will issue, upon request, export authorizations for products included in the register. The Medicines Agency may delete a product if it does not fulfill conditions for listing in the register.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

There are no special rules for trans-shipped medicinal products. Import and re-export are governed by the regulations described above.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

From the information available, it would seem that these regulations governing export of medicinal products are administered in the same way as the other rules of the legislation governing medicinal products.

**Finland**

*Pekka Puhakka*

*Attorneys' House ANPR Ltd*

*Tel: +358 9 474 21*

*Email: pekka.puhakka@anpr.fi*

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines Act (395/1987) and the Medicines Decree (693/1987) provide the legislative basis for control of medicinal products, including their manufacture, import, distribution, sale and release for consumption. This regulation also applies to medicinal products that are intended only for export.

A license granted by the National Agency for Medicines ("NAM") is required for industrial manufacture and/or wholesale trade of medicines. Import of medicines is permitted only by those entitled to manufacture or wholesale distribute medicines.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

A medicinal product may be sold to the public or otherwise released for consumption only if the product has been granted a marketing authorization by the NAM or EU. A marketing authorization is not required for import or export of a medicinal product.

- (b) **must manufacturers of such products hold a manufacturer's authorization?**

A manufacturer's authorization granted by the NAM is required for industrial manufacture of a medicinal product. This applies to products intended for the Finnish market, as well as to products intended for export. A manufacturing license is granted to a specific company for specific medicinal products. The criteria for such authorizations are similar, whether the products are intended for the domestic market or for export.

- (c) **must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Manufacturers of medicinal products must comply with European GMP, which may be supplemented by specific orders from the NAM. The standard of GMP is the same whether the products are intended for the domestic market or for export.

- (d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Only those that are authorized to manufacture medicines and/or to conduct wholesale trade may import medicines. As mentioned earlier, a license is required for both the manufacture and wholesale trade of medicines, including export. The holders of wholesale trader's authorizations must comply with European GMP.

- 3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

There are no government pre-notification or pre-approval requirements that must be fulfilled prior to the export of medicinal products. The NAM may issue certificates about products and their manufacturing, if requested by manufacturers, wholesalers, or the authorities of foreign countries. Obtaining a certificate is not a requirement for export.

- 4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The Medicines Act includes no specific provisions relating to medicines that are imported solely for subsequent export. Under the general rules dealing with trans-shipping of products across Finnish jurisdiction, one may merely trans-ship medicinal products *via* Finland without obtaining any license or permission from the NAM or any other Finnish authority and without such products becoming subject to Finnish regulation.

- 5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

The NAM and the Customs Administration have the power to make inspections, etc., in order to ensure that any import, manufacture, and wholesale trade of medicines that takes place in Finland complies with the provisions of the Medicines Act. The intensity of the supervising measures is not affected by whether the products are intended for the domestic market or for export.

## France

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The French Public Health Code ("*Code de la santé publique*" or "CSP") provides the legislative basis for control of medicinal products through a system of authorizations. Amongst other things, it is unlawful for medicinal products to be imported, marketed, manufactured, distributed, sold, supplied in, or exported from, France except in accordance with the appropriate approvals, unless an exemption applies.

The Medicines Agency ("*Agence Française de Sécurité Sanitaire et des Produits de Santé*" or "AFSSAPS") is responsible for issuing licenses to those engaged in the manufacture, sale, import, or export of medicinal products. It also conducts inspections to ensure that authorization holders comply with the terms of their licenses.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

*Supply.* According to article L. 5121-8 of the CSP, no medicinal product may be marketed or distributed for free, by way of wholesale or retail, unless a marketing authorization for that product has been granted by the AFSSAPS or the European Commission. The term "marketed ... by way of wholesale or retail" is not defined under French law but is generally understood to involve transfer of the product to a third party.

*Import.* Article L. 5124-13 of the CSP provides that import of medicines into France is subject to the AFSSAPS's prior authorization. A French marketing authorization is equivalent to an import authorization. Thus, while marketing authorizations are not required to import medicinal products into France, they exempt the importer from the obligation to request an import authorization from the AFSSAPS.

Pursuant to article R. 5142-14 of the CSP, a request for import authorization must include the following: the name and address of the person responsible for the import; the country of export and, as the case may be, the country of origin; the name, composition, pharmaceutical form, dosage, and administration methods of the medicine; the imported quantities; and the purposes of import. The request must be accompanied by a letter explaining the intended use of the product and/or the reason for the import. The authorization may be denied if the medicine is or may be harmful to public health.

*Export.* No marketing authorization is required for the export of products outside of France. However, pursuant to article L. 5124-11 of the CSP, a pharmaceutical company that exports a medicine must request that the AFSSAPS certify that the company is

authorized to operate a pharmaceutical establishment (see below). In addition, for medicinal products without marketing authorizations, the exporter must notify the AFSSAPS of the reasons why the French marketing authorization is unavailable, so that the AFSSAPS may inform the Ministry of Health of the importing country. The AFSSAPS may prevent the export if the medicine does not have a marketing authorization or presents risks disproportionate to its expected benefit.

**(b) must manufacturers of such products hold a manufacturer's authorization?**

Article L. 5124-1 of the CSP provides that only a pharmaceutical establishment may manufacture, import, export, and wholesale distribute medicines. Article L. 5124-3 states that the operation of a pharmaceutical establishment is subject to an authorization delivered by the AFSSAPS. Thus, all manufacturers of medicinal products must hold a manufacturer's authorization granted by the AFSSAPS, even if the product is being manufactured only for export.

Article R. 5106 lists and defines thirteen categories of pharmaceutical establishments. Each category corresponds to specific activities/obligations and is subject to an authorization from the AFSSAPS.<sup>1</sup> Manufacturers are one category, and are defined as companies that manufacture medicines for wholesale, retail, or clinical trials purposes. Manufacturing operations include purchase of materials, production, quality control, batch release, and related storage activities.

Importers are a different category of establishment, and are defined as companies that import, store, control the quality, and release batches of medicines originating from outside France for wholesale, retail, or clinical trials purposes. Consequently, manufacturers may not import finished drug products unless they hold an import authorization in addition to the manufacturing authorization.

Where a finished product is imported from a non-EEA country under an import authorization, article R. 5115-7 requires the importer to ensure that the manufacturing operations outside the EEA have been carried out by a duly authorized manufacturer, that the products have been manufactured in accordance with European GMP, and that each production batch has undergone a full qualitative analysis and a quantitative analysis of at least the active ingredients.

---

<sup>1</sup> A pharmaceutical establishment that falls simultaneously into several categories (for example, an establishment that both manufactures products and sells them to a wholesale distributor in France or exports them outside of the EU) must obtain an authorization for each category. The AFSSAPS, however, may grant a single authorization to cover all necessary categories.

- (c) **must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Article L. 5121-5 of the CSP provides that the manufacture, import, and distribution of medicines must be carried out in conformity with the good practices set forth in ministerial ordinances. Holders of a manufacturing authorization must thus comply with European GMP set forth in a ministerial ordinance of May 10, 1995 on GMP, as amended. The authorization holder must ensure conformity with the standards of strength, quality and purity applicable to them under relevant marketing authorizations and in accordance with European standards of GMP.

- (d) **must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

As explained above, article R. 5106 distinguishes among thirteen categories of pharmaceutical establishments on the basis of the particular activities they engage in. Each category requires a separate authorization from the AFSSAPS. The categories include, among others, wholesale distributors and wholesale distributors for export purposes.

Wholesale distributors include two kinds of distributors: those who purchase and store finished products for resale by wholesale dealing (“*grossistes-répartiteurs*”) and those who store finished products on behalf of manufacturers, importers, or operators for wholesale purposes (“*dépositaires*”). Wholesale distributors for export purposes are those companies that purchase and store finished products for export purposes. An AFSSAPS authorization is required for each of these categories.

Article R. 5106-2 authorizes manufacturers, importers, and wholesale distributors to export their medicines from France. However, wholesale distributors for export purposes must be authorized for such activity.

Article L. 5121-5 requires that the distribution of medicines, including export, be conducted in conformity with the good practices set forth by ministerial ordinances. Authorized wholesale distributors must fulfill the obligations contained in a ministerial ordinance of June 30, 2000 on good wholesale distribution practices, as amended. These obligations include providing and maintaining suitable staff, premises, equipment and facilities, etc.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Pursuant to article L. 5124-11, export of medicinal products is subject to the following requirements:

- (i) the AFSSAPS must issue a certificate that states that the exporter holds an authorization for a pharmaceutical establishment;

- (ii) for medicines without French marketing authorization, the exporter must notify AFSSAPS of the reasons why a marketing authorization is not available.

The AFSSAPS will also issue export certificates (so-called "*certificates de libre vente*") on request to assist exporters in satisfying import requirements in other countries. However, there is no French legal requirement that such certificates be obtained and they are only issued for products with marketing authorization.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from its jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Medicines imported into France solely for subsequent export are subject to a separate regime, which depends on whether they are imported from another country within the EEA.

Article R. 5142-2 of the CSP<sup>2</sup> provides that medicines other than finished products (i.e., medicines that have not yet been subject to all the manufacturing stages including conditioning) and medicines designed to be stored in a national import warehouse pursuant to article 277 A of the General Tax Code, require an import authorization. An import authorization is valid only for a set number of anticipated import transactions and for a given aggregate quantity, over a period of up to one year. Authorizations are renewable but must be surrendered to the AFSSAPS at the end of the transactions or the expiry of the relevant period. At that time, the importer also must indicate the quantities actually imported and the dates of import.

This regime is more favorable than the regime for other imports of finished medicinal products. An authorization, which is only valid for three months, is required for every import that is not stored in a customs warehouse.

Article R. 5142-2 does not distinguish between import from an EEA country and import from a non-EEA country. However, according to an official at the AFSSAPS, whom we contacted on an anonymous basis, article R. 5142-2 does not apply to products imported from non-EEA countries. Products imported from non-EEA countries for export to non-EEA countries are not subject to public health rules as long as they remain in a customs warehouse, on the basis that they do not enter France. No authorization relating to public health is required for importing and exporting such medicines. Nonetheless, the importer/exporter must comply with the customs warehouse rules.

---

<sup>2</sup> Inserted by Decree No. 2004-83 of January 27, 2004 on import of medicines for human use.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a French manufacturer's or wholesale dealer's or importer's authorization is required, the AFSSAPS Inspectorate will conduct inspections prior to granting an authorization and on a regular basis thereafter. These inspections are intended to ensure that authorization holders comply with the conditions of the authorizations, with the provisions of French law, and with GMP or GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Germany

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines Law (*Arzneimittelgesetz* or “AMG”) is the primary legislation regulating the manufacturing, importation, placing on the market, and exportation of medicinal products.

The Federal Institute for Medicinal Products and Medical Devices (*Bundesinstitut für Arzneimittel, und Medizinprodukte* or “BfArM”) is responsible for granting marketing authorizations for all products except immunological products, vaccines and blood products, which are regulated by the *Paul Ehrlich Institut* (“PEI”). The regional authorities grant manufacturing licenses.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

Article 21 of the AMG provides that no products may be placed on the market without a marketing authorization. The term “placing on the market” includes wholesale distribution.

According to *Kloesel/Cyran*, one of the leading commentaries in the medicines field, no marketing authorization is required if the product is solely intended for export.<sup>1</sup> However, a manufacturer is free to apply for a marketing authorization, if a marketing authorization in the country of export is a prerequisite for the importation.<sup>2</sup>

A marketing authorization is also required for products imported into Germany, subject to specific exemptions for products for personal use, and limited samples for the purpose of analytical testing or official batch testing.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

According to section 13 of the AMG, a manufacturer’s authorization is required to manufacture medicinal products. This obligation applies to the manufacture or assembly of any medicinal product irrespective of whether it is intended for export.<sup>3</sup>

---

<sup>1</sup> Note 23 to section 21 of the AMG.

<sup>2</sup> Kloesel/Cyran, Note 25 to section 21 of the AMG.

<sup>3</sup> Kloesel/Cyran, Note 3 to section 13 of the AMG.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Section 1 of the Pharmaceutical Manufacturing Ordinance (*Pharmabetriebsverordnung*) requires manufacturers of medicines to implement a system that guarantees the quality of the medicines. The *Pharmabetriebsverordnung* does not specifically define the system. According to *Kloesel/Cyran*, the quality system must include GMP. German GMPs are found in the Announcement of GMP guidelines for pharmaceutical products of the pharmaceutical inspection convention (*Bekanntmachung des Leitfadens einer Guten Herstellungspraxis für pharmazeutische Produkte der Pharmazeutischen Inspektions-convention*, or “PIC Guidelines”).<sup>4</sup>

Where products are intended for export, manufacturers must comply with sections 5 and 8(1) of the AMG, rather than with section 1. Section 5 prohibits the marketing of unsafe products and section 8 prohibits the manufacturing of medicinal products that:

“by deviating from recognized pharmaceutical principles, are significantly diminished in their quality.”

According to *Kloesel/Cyran*, significant deviations from the GMPs set out in the PIC Guidelines could diminish product quality.

Deviations from sections 5 and 8 are permitted, provided the competent authority in the country of importation agrees to the importation of product of diminished quality (section 73a of the AMG).

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Currently, no license is required for the export of medicinal products. Product export is subject only to the supervision of the customs authorities.

However, this will change in the near future. According to the draft law amending the AMG, wholesalers will need to obtain a wholesale license from the competent regional authority. A new definition of wholesale will encompass the exportation of medicinal products. The new article 52a of the AMG will require that wholesalers comply with good distribution practices.

---

<sup>4</sup> By law of 1983, Germany joined the PIC. The PIC GMP guidelines are in line with the EU GMP. Every chapter of the PIC GMP guidelines gives basic rules for GMP, which are then further explained.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic, or other controlled substance, no German government pre-notification or pre-approval requirements must be fulfilled prior to the export of medicinal products.

If necessary to comply with laws in the destination country, export certifications may be issued, on request, either by the BfArM or the PEI.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

In general, products without a valid marketing authorization may not be imported unless one of the exemptions in section 73(2) of the AMG applies. According to 73 (2) Nr. 3 of the AMG, (i) products transported under the supervision of the customs authorities; and (ii) products exported after transit storage in customs depots or bonded warehouses are exempt from the marketing authorization requirement. These products still must comply with the basic requirements in sections 5 and 8 of the AMG (see section 2 above). This means that the German competent health authorities have the power to inspect products while in transit storage. Therefore, the person holding the import authorization should ensure that the products comply with sections 5 and 8 upon their import into Germany.

**5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a German manufacturer's license is required, the regional authorities will conduct inspections prior to the grant of the license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with the provisions of German law, and with European GMP or GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Greece

*Geena Papantonopoulou*

*Calavros and Partners*

*Tel: +30 2 10 369 8700*

*E-mail: papantonopoulou@calavros.com*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The basic Greek legislation regulating the circulation of medicinal products for human use is Legislative Decree No 96/1973 (governing medicinal products intended for the domestic market which are either locally produced or imported) and the ministerial decision A6a/9392/1991 (governing medicinal products for human use intended for the domestic market). The term "circulation," under Greek law is defined in article 1 of the Legislative Decree 96/1973, and includes all acts of a medicinal product's transfer from the producer up to the final consumer-patient.

Greek pharmaceutical law does not include provisions specifically regulating the import, manufacture, distribution, supply, or shipment of medicines that are intended only for export from Greece.

Explicit references to *exports* of medicinal products from Greece are found in:

- (i) the Law 1316/1983 on the "Foundation, organization and authorities of the National Drug Organization (EOF) etc." Articles 2 and 3 state that all pharmaceutical products fall within EOF's jurisdiction, regardless of whether: (i) they are produced or imported in Greece as raw materials, semi-finished or ready made products, or (ii) they are traded within or outside Greece, or (iii) they are intended for domestic consumption or export.
- (ii) Article 10 of ministerial decision A6a/9392/91/92 states that the manufacturing or assembling of medicinal products in Greece is permitted only after EOF issues a manufacturing license, regardless of whether such products are intended for export from Greece.

According to article 3 of the ministerial decision A6a/9392/91/92 as in effect, the circulation of medicinal products for human use (whether locally produced or imported) in the domestic market requires a circulation license from the EOF. In essence and in practice, a circulation license is a "marketing license."

- 2. If the laws in your jurisdiction apply to products intended only for export:**
  - (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization**

**and approval process and the standards that are applied differ from those for products intended for your domestic market?**

As already noted, there is no marketing authorization requirement under Greek law for medicinal products intended solely for export. A circulation (marketing) authorization is required before a medicinal product for human use (locally produced or imported) can be supplied or marketed in Greece, but technically, circulation licenses are not required prior to the mere act of importing medicinal products into Greece.

**(b) must manufacturers of such products hold a manufacturer's authorization?**

Under article 10 of ministerial decision A6a/9392/91/92,<sup>1</sup> a medicinal product may be manufactured or assembled in Greece only if the interested party holds a manufacturer's license issued by EOF. This obligation applies to the manufacture or assembly of any medicinal product, irrespective of whether it is intended for the domestic market or for export.

Paragraph 2 of article 10 of this ministerial decision provides that applicants for manufacturing licenses must provide EOF with, amongst other things: (a) details of the product and the forms in which the product will be manufactured or imported, as well as the place of manufacture and control; and (b) detailed information about the efficiency and adequacy of the production and control facilities, the technical equipment, the required personnel and the capability to produce, control and store the product. EOF will usually only issue a manufacturer's license after inspecting the site and verifying that the information contained in the application is accurate and in compliance with legal requirements.

The EOF conducts inspections to ensure that license holders comply with the terms of their licenses.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Manufacturing license holders are obliged, under article 11(g) of ministerial decision A6a/9392/91/92, to comply with the European principles of GMP for medicinal products. These principles are set out in ministerial decision No. Y6/11228/1992.<sup>2</sup>

Medicinal products manufactured in Greece must be manufactured in accordance with European GMP, regardless of whether they are intended for domestic use or for export.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

---

<sup>1</sup> This ministerial decision implemented Directive 75/319/EEC.

<sup>2</sup> This ministerial decision implemented Directive 91/356/EED.

As noted above, no marketing or other government authorization is required under Greek law to export medicinal products.<sup>3</sup>

A pharmaceuticals wholesaling business may distribute medicinal products only under a license issued by the Ministry of National Health, according to article 2 of the legislative decree 363/1941 as in effect.

According to article 27 of the Law 1316/1983, any person involved in the production, trade, or distribution of pharmaceutical products, must maintain detailed records for receiving, controlling, and distributing such products. The wording of this provision implicitly covers exporting activities from Greece, as well. In line with this law, EOF issued circular No 40033/2001. Under this circular, wholesalers must report their medicinal product exports quarterly to EOF.

Further, under article 2 of the ministerial decision Y6/2610/1993, any person (whether or not the holder of a circulation or manufacturing license) who transfers or transports medicinal products from or to an EU Member State must officially inform EOF within 5 days from the product's arrival in Greece. The person must provide such details as (a) product name, form, and composition; (b) manufacturer's name; (c) copies of transporting invoices; (d) circulation license number in Greece; (e) date of import to/export from Greece; (f) batch number; (g) name and address of final receiver; and (h) certificate of the quality and safety of the particular product batch etc.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no government pre-notification or pre-approval requirements that must be fulfilled under Greek law prior to exporting medicinal products from Greece.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

There is no indication that Greek law licensing and control requirements apply in the case of trans-shipment of products *via* Greece. As long as the products are not subject to any "manufacturing alteration"<sup>4</sup> while they are in Greece, and are exported in the same form in which they were imported, the products are not subject to any licensing or control requirement within Greece.

---

<sup>3</sup> Special procedures apply for the transfer of radioactive material and pharmaceutical products containing radium through EU member states or into Greece from third countries. These products must be transferred, stored, and transported via the Greek Committee of Atomic Energy according to article 6 of ministerial decision Y6/2610/1993.

<sup>4</sup> Products subject to manufacturing alterations are governed by article 10 of the ministerial decision A6a/9392/91/92, and the interested party must obtain a manufacturing license.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that exported products are manufactured in Greece, EOF conducts inspections prior to granting a manufacturer's license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with Greek law, and with European GMP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

**Iceland**

*Gudrun Ásta Sigurdardóttir*

*Tel: +588 8910*

*Email: gudrun@fis.is*

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Regulation concerning marketing authorizations for proprietary medicinal products, their labelling and package leaflets, no 462/2000 ("the Regulation") and the Medicinal Products Act no 93/1994 ("the Act") provide the legislative basis for control of medicinal products through a system of licenses and authorizations. Amongst other things, it is unlawful for medicinal products to be imported, marketed, manufactured, distributed, sold, supplied in, or exported from, Iceland except in accordance with the appropriate approvals, or under an exemption.

The Medicines Control Agency regulates medicinal products for human use. Its duties include the issuance of licenses to those engaged in the manufacture, sale, or supply of medicinal products, and the conduct of inspections to ensure that license holders comply with the terms of their licenses.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to section 7 of the Medicinal Products Act, no medicinal product can be placed on the market or distributed by way of wholesale dealing unless a marketing authorization for that product has been granted by the Medicinal Control Agency. The term "wholesale dealing" encompasses the sale of a medicinal product in the course of a business to a person who buys it for sale or supply or for administration to a human being. The term "place on the market" is not defined under Icelandic law, but is generally understood to involve the transfer of product to a third party.

A marketing authorization is therefore required before a product can be supplied or marketed in Iceland. Technically, marketing authorizations are not required prior to the mere act of import or export into or from Iceland. Therefore, there is no marketing authorization requirement for products intended solely for export.

- (b) **must manufacturers of such products hold a manufacturer's authorization?**

Chapter XII of the Medicinal Products Act requires any person who manufactures or assembles a medicinal product to hold a manufacturer's license. This obligation applies

to the manufacture or assembly of any medicinal product, whether intended for export or not.

According to the Regulation on Manufacturing of Medicinal Products no 700/1996, applicants for manufacturing licenses must provide the Ministry of Health and Social Security with detailed information about the production and/or control of the pharmaceutical manufacturing operations. The Ministry will only issue a manufacturer's license when it is satisfied that the information contained in the application is accurate and in compliance with legal requirements. Issuance usually follows an inspection of the site.

Under European Community law (which has been made part of Icelandic legislation in accordance with the EEA Agreement), importation of a medicinal product from outside the EEA is considered to be a manufacturing operation. This is reflected in §16-19 of Regulation on Import and Wholesale Distribution of Medicinal Products no 699/1996, which requires importers of medicinal products from outside the EEA to hold a wholesale dealer's import license, which is equivalent to a manufacturer's license.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Holders of a manufacturing license must comply with the requirements set out in the Regulation on Manufacturing of Medicinal Products. The license holder must conduct all manufacturing and assembly operations in such a way as to ensure conformity with the standards of strength, quality and purity applicable under the relevant marketing authorizations and in accordance with European GMP.

Where product is imported from outside the EEA, the license holder must ensure that the manufacture and assembly operations outside the EEA have been carried out by a duly authorized manufacturer or assembler; that the products have been manufactured and assembled in accordance with European GMP; and that each production batch has undergone a full qualitative analysis as well as a quantitative analysis of at least all the active ingredients. Unless Iceland has entered into a Mutual Recognition Agreement with the originating state, the importer must perform all other tests or checks necessary to ensure that the quality of the product satisfies the requirements of any relevant marketing authorization and that it has been manufactured in accordance with GMP. All testing and quality control operations must be in accordance with European GMP.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Chapter XI of the Medicinal Products Act requires that any person distributing medicinal products by way of "wholesale dealing" obtain a wholesale dealer's license. Distribution by way of wholesale dealing includes any act of selling or supply, or procuring, holding or exporting a product for the purpose of sale or supply.

Authorized wholesaler dealers must fulfill the obligations contained in Chapter 5 of the Regulation on Import and Wholesale Distribution of Medicinal Products no 699/1996.

The dealer must provide and maintain suitable staff, premises, equipment and facilities and comply with good distribution practices ("GDP"). The current GDP requirements set out in European Commission guidelines are intended to ensure that product quality is unaffected by storage and transportation.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no Icelandic government pre-notification or pre-approval requirements that must be fulfilled prior to the export of medicinal products. There are, furthermore, no Icelandic legal requirements for export licenses or certificates.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Trans-shipment of products *via* Iceland is currently not subject to any licensing or oversight, unless the products are subjected to a manufacturing operation. In that case, a manufacturing license would be required.

**5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that an Icelandic manufacturer's or wholesale dealer's license is required, the Medicines Control Agency will conduct inspections prior to the grant of the license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with the provisions of Icelandic law and with European GMP and GDP, as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Ireland

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The manufacture, importation, distribution, and supply of medicinal products for human use in Ireland is regulated by the Irish Medicines Board ("the IMB"). The IMB is the licensing authority for medicinal products for human use in Ireland pursuant to the provisions in the Irish Medicines Board Act 1995.

The Medicinal Products (Licensing and Sale) Regulations (S.I. 142 of 1998), as amended, ("the Sale Regulations") and relevant EC Directives regulate the licensing and sale of medicinal products. The Medicinal Products (Licensing of Manufacture) Regulations (S.I. 40 of 1993), as amended, ("the Manufacture Regulations") regulate the manufacture of medicinal products. The Medicinal Products (Wholesale Licenses) Regulations (S.I. 39 of 1993), as amended, ("the Wholesale Regulations") regulate wholesale distribution of medicinal products.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to article 3 of the Sale Regulations, no person may, in the course of business, import, place on the market, or otherwise sell any medicinal product, or procure the manufacture for sale of any medicinal product, unless the product has a "product authorization" from the IMB or a marketing authorization from the European Agency for the Evaluation of Medicinal Products. The term "manufacture" includes the importation of a medicinal product from a country other than an EC Member State.

A product or marketing authorization is therefore needed before a product can be imported, supplied, or marketed in Ireland. Such authorizations are not required, according to article 4(d) of the Sale Regulations, where a medicinal product is imported or sold solely for the purpose of exportation.

- (b) **must manufacturers of such products hold a manufacturer's authorization?**

Article 4 of the Manufacture Regulations requires that any person who manufactures for sale any medicinal product must hold a "manufacturer's license" granted by the IMB.<sup>1</sup>

---

<sup>1</sup> "Manufacture" includes total and partial manufacture; the various processes of dividing up, packaging or presentation; formulation, processing, compounding or filling; and the importation of a medicinal product from a country other than a Member State of the EC.

This obligation applies whether the product is intended for export or not. Importation of a medicinal product from outside the EC is considered to be a manufacturing operation and requires a manufacturer's license.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Holders of a manufacturing license must comply with the requirements set out in Schedule I of the Manufacture Regulations. Paragraph 5 of Schedule I requires the license holder to provide and maintain premises, equipment, facilities and staff as are necessary to carry out the tests on the medicinal product required by the relevant product authorization, and for compliance with European GMP. Alternatively, the tests may be carried out by another person on the license holder's behalf, if approved in writing by the Minister for Health.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

According to article 4 of the Wholesale Regulations, no person is allowed to keep or offer for sale by wholesale, or sell by wholesale, any medicinal product except in accordance with a "wholesaler's license." The term "sale by wholesale" includes exportation of medicinal products.

An importer who does not own the products and acts solely as a carrier or import agent for products imported from third countries (i.e. outside the EC or EEA) is not required to hold a wholesaler's license as long as the products are delivered to a licensed manufacturer or wholesaler. However, an import agent who holds medicinal products for an appreciable length of time (more than 48 hours) must hold a wholesaler's license.

A license holder must comply with the provisions set out in article 7(2) of the Wholesale Regulations. The license holder must provide and maintain suitable premises, equipment and staff, and comply with good distribution practices ("GDP"). The current GDP requirements are set out in European Commission guidelines and are intended to ensure that product quality is unaffected during storage and transportation.<sup>2</sup>

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

No government pre-notifications or pre-approvals are required. A company may apply to the IMB for an export certificate for a medicinal product or for an active pharmaceutical ingredient. However, this certificate is not legally required.

---

<sup>2</sup> See <http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2001/may/GDPGuidelines1.pdf>.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

A product authorization or marketing authorization is not required for the trans-shipment of products *via* Ireland. Article 4(d) of the Sale Regulations provides that the requirements imposed by article 3 of the Sale Regulations do not apply to the importation or sale of a medicinal product solely for the purpose of export.

If a medicinal product is imported from a third country (i.e. outside the EU or the EEA), a manufacturer's license will be required, irrespective of whether the product is re-exported.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that an Irish manufacturer's or wholesaler's license is required, the IMB will conduct inspections prior to granting a license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with the provisions of Irish law, and with European GMP or GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

**Israel**

*Dina Mass*

*Email: dinamass@bezeqint.net*

*Tel: 972-9-9587924*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The two statutes governing regulatory issues at large and the issue at hand are The Pharmacopia Ordinance [New Version] 1981 (“the Ordinance”) and The Pharmacists Regulations [Medicinal Preparations] 1986 (“the Regulations”). The General Manager of the Ministry of Health (“the Manager”) has implemented the Regulations through rules and directives.

The Regulations detail the terms and conditions for registering a medicinal product in the National Drug Booklet (“Booklet”). The Directives also establish registration requirements. The primary Directive is the Procedure for the Registration of Medicinal Products – 1991.

The manufacture, packaging, and control of finished pharmaceuticals (pharmaceutical products) and Active Pharmaceutical Ingredients (APIs) for human, biological, and veterinary drugs, is regulated by the Pharmaceutical Division of the Israeli Ministry of Health.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for Israel’s domestic market?**

Under section 47A of the Ordinance, medicinal products may be marketed only under a marketing authorization and in accordance with the product’s registration terms and the Regulations. “Marketing” is defined in the Ordinance and Regulations as “the sale, supply, import, export or the transfer of ownership or possession.” Thus, a marketing authorization is required before medicinal products can be imported, supplied, or exported.

Sec. 29(a)(6) to the Regulations provides an exemption from registering a medicinal product that is manufactured in Israel but is intended for export. The exemption is subject to the Manager’s consent. A Notice describing the requirements for receiving the Manager’s consent was published in the Law Digest – 1999 2<sup>nd</sup> page. The manufacturer must provide the Manager with proof that the medicinal product is safe for its intended

purpose, and either is registered in the territory to which it is being exported, or is authorized for import by the authorities in that territory.

Thus, according to the Ministry, medicinal products manufactured in Israel but intended for export can be approved in two different ways:

1. Through registration in Israel, in accordance Ministry requirements for domestic products. This requires a Certificate of Pharmaceutical Products ("CPP") approval; or
2. Under the exemption in Sec. 29(a)(6), as described above. The exporter must show that the medicinal product is safe, in that it is manufactured in an approved/licensed manufacturing plant and is suitable to be registered in Israel, or has been approved for marketing by the authorities of the territory to which it is being exported.

Under section 47B(b) of the Ordinance, a registered medicinal product may only be imported by the registrar of the medicinal product listed in the Booklet, by the product's importer in accordance with Sec. 47C, or by a Pharmaceuticals dealer or a Known Establishment.<sup>1</sup>

**(b) must manufacturers of such products hold a manufacturer's authorisation?**

Any business that produces or processes medicinal products, including raw materials, accessories, medical equipment and any accompanying items or substances, must hold a permit, under The Order for Business Permit (Permit Requiring Business) – 1995, Appendix Sec. 1.2.a.

Manufacturing is defined in both the Ordinance and the Regulations to include "combining, mixing, integrating, refining, processing, change of form and operating any physical or chemical process for the preparation or packaging of a medicinal product."

The business must apply to the local municipality for a permit. The municipality will refer the applicant to The Institute for Standardization and Control of Pharmaceuticals ("The Institute"), within the Pharmaceutical Division of the Ministry. The Institute then investigates whether the manufacturing plant in is in compliance with good manufacturing practice ("GMP"). The manufacturing processes are subject to a strict permit control by the Ministry.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Israel has adopted GMP rules and the Ministry has published a detailed Directive regarding Israeli GMP requirements (Inspection Manual, January 2003, or "the Manual"). The Manual does not distinguish between products intended only for export and those

---

<sup>1</sup> Known Establishment is a technical term which refers to hospitals or other health institutes.

intended for domestic use. The only exemption regarding export is specified in Sec. 29(a)(6) to the Regulations, described above in section 2(a). Under this exemption, a product intended only for export may be manufactured according to the manufacturing requirements of the country of export, rather than under Israel's GMP.

The Institute has authority and responsibility for compliance and enforcement of current GMP regulations. Manufacturing plants are subject to periodic inspections, performed at the Ministry's discretion. The Manual outlines procedures for these compliance inspections.

**(d) must distributors or exporters of such products hold a government authorisation and must good distribution practices be followed?**

The distribution of medicinal products in Israel requires special permits, as discussed in the Ordinance and the Regulations. Medicinal products dealers (as well as drugstores) must have a special business permit. The permit is conditioned upon appropriate transport and storage of the product.

Under section 47B(d) of the Ordinance, wholesale of medicinal products may be conducted via pharmaceutical dealers or Known Establishments.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Other than the marketing authorization requirements described above, no prenotification or pre-approval of export generally is required.

If the Medicinal Product/process contains narcotic or psychotropic substances the dealer must report the export, under the Dangerous Narcotic Ordinance [New Version], 1978 Sections 4 and 15-18.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from its jurisdiction, i.e. where products are merely trans-shipped across its jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

To the best of our knowledge there are no rules regarding trans-shipped products. Such products will not be regulated as they will not actually enter Israel's territory. However, if the products do enter Israel's territory and, for example, undergo packaging or re-packaging, all regulatory requirements will apply.

The only exception to this rule stems from the special understanding between Israel and the Palestinian Authority. According to the Paris Agreement, medicinal products trans-shipped *via* Israel to the Palestinian Authority undergo Israeli regulatory inspection system and approvals.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

Except as specified in section 4 above, Israel's regulatory system does not address the concept of trans-shipment. Trans-shipped products are not within Israel's jurisdiction, and therefore receive no recognition, approval, or disapproval by Israel's authorities.

However, since dealers of medicinal products must have a permit in accordance with the Business Permit Order Sec. 1.3, such dealers' activities are regulated by the Regional Health Authorities. The businesses will be subject to periodic inspections by these Authorities.

Furthermore, under section 46 of the Ordinance, the Manager has authority to visit businesses involved or suspected of involvement in the business of medicinal products or toxic drugs, to ensure that all such businesses have a valid permit. The Manager may take samples of the products for inspection.

**Italy**

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

Legislative Decree 178/1991, as amended, regulates the manufacture of medicinal products, even if they are intended for export. A Decree of the Ministry of Health of 1996 and a Decree of 2002 establish the requirements and application procedures to obtain an authorization to manufacture medicinal products intended for export. The Ministry of Health is responsible for granting authorizations for the manufacture of medicinal products.

Legislative Decree 538/1992 on the wholesale distribution of medicinal products regulates the warehousing, keeping, distribution, and export of medicinal products. A Circular of the Ministry of Health of 1993 makes clear that Legislative Decree 538/1992 also applies to persons that are solely engaged in the export of medicinal products, if they keep medicines in warehouses in Italy. The Italian Regions are responsible for the granting of authorizations for distribution of medicinal products under Legislative Decree 538/1992.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

Article 8 of Legislative Decree 178/1991, as amended, prohibits the placing on the Italian market of medicinal products that have not obtained an Italian or EU marketing authorization.

Article 18 makes clear that a marketing authorization is also required to place an imported medicinal product on the Italian market. Imported medicinal products are subject to the same requirements for marketing authorization as products manufactured in Italy. "Placing on the market" is generally understood to mean making the product available to a third party within the Community. Thus, marketing authorization is not required merely to import the product.

Article 25(4) makes clear that medicinal products intended for export do not require a marketing authorization.

- (b) must manufacturers of such products hold a manufacturer's authorization?**

Legislative Decree 178/1991 prohibits the manufacture of medicinal products in Italy without a manufacturing authorization from the Ministry of Health. It makes clear that the requirement of an authorization also applies to the manufacture of medicinal products

that are intended for export. This was confirmed by a judgment of the Court of Appeal of Milan in 2000.

A Decree of the Ministry of Health of 1996 and a Decree of 2002 establish the requirements and application procedures to obtain an authorization to manufacture medicinal products intended for export.

Legislative Decree 178/1991 also requires that importers obtain an authorization to import medicinal products into Italy. This authorization is required even if the medicinal product will not be marketed in Italy. However, an authorization is not required if (1) the product is imported from another EU Member State where it was manufactured; (2) the product is imported from, but was not manufactured in, another EU Member State and that Member State has granted a certificate of quality control; or (3) the product is imported from a non-EU Member State with which Italy has entered into an agreement ensuring the quality of medicinal products. The application for authorization must specify the medicinal products to be imported, but an application is not necessary for each import operation. The granting of an authorization is subject to compliance with quality manufacturing controls.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Legislative Decree 178/1991 requires the Ministry of Health to monitor all authorized manufacturers of medicinal products, including manufacturers of medicinal products intended for export, for compliance with European GMP.

Importers of medicinal products from non-EU countries must control the quality of imported products held in Italy, under Legislative Decree 178/1991. The establishments holding the products must be approved by the Ministry of Health.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

According to Legislative Decree 538/1992 on the wholesale distribution of medicinal products, any person who keeps in warehouses, distributes, or exports medicinal products must obtain an authorization from the relevant Region. The distributor must comply with good distribution practices, which are detailed in a Decree of the Ministry of Health of 1999.

These requirements also apply to persons that keep warehouses in Italy and engage only in the export of medicinal products, according to a Circular of the Ministry of Health of 1992. The Decree does not apply to traders who do not keep medicinal products in warehouses in Italy.

3. **Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

We are not aware of Italian legislation requiring government pre-notification or pre-approval for the export of medicinal products other than narcotics, psychotropic, and other controlled substances.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

There are no specific rules on trans-shipped products. Legislative Decree 178/1991 requires that importers of medicinal products obtain an authorization from the Ministry of Health. This requirement applies equally to importers of products imported solely for re-export. Similarly, Legislative Decree 538/1992, which applies to any person engaged in the warehousing, distribution, or export of medicinal products, does not exempt persons that import medicinal products solely for subsequent export.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

We have no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

**Japan**

*Masaru Kitamura*

*KitamuraLaw*

*Tel: 81-3-3580-4567*

*E-mail: masaru@kitamuralaw.com*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Pharmaceutical Affairs Law (the “Law”) does not directly regulate exportation of medical products, but indirectly applies to the act of manufacture or importation for the purpose of (re-)exportation. For such manufacture or importation, Article 80 of the Law provides that drugs, “quasi-drugs,” cosmetics or medical devices may be exempted from the Law by cabinet order.<sup>1</sup> The Ministry of Health, Labor, and Welfare administers the Law via its various Bureaus and Centers, notably the Pharmaceutical and Medical Safety Bureau and the Drug and Medical Device Examination Center.

Article 15 of the Enforcement Order of the Pharmaceutical Affairs Law (a cabinet order) provides that no product approval is required for the manufacture/importation of medicinal products that are intended for (re-)export. However, this provision does not exclude such manufacture/importation from the licensing and related GMP requirements.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

A “marketing authorization” (approval) is required only for products intended for domestic consumption. No marketing authorization is required to import or export products. However, the manufacturer/importer is required to file a notification of the products he intends to manufacture or import for the purpose of (re-)export.

- (b) must manufacturers of such products hold a manufacturer’s authorization?**

The manufacturer/importer must possess a proper license for the business, as required by Articles 12 and 22 of the Law. Japanese GMP and other regulatory requirements that apply in connection with the license will also apply to the manufacturing/importation of medical products.

---

<sup>1</sup> Importation of narcotics and other controlled substances is prohibited.

- (c) **must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

The Law establishes a set of minimum requirements for medicinal products, such as the prohibition of sale of unsanitary or contaminated products (Article 56). These principles apply equally to medicinal products intended for (re-)export. The Manufacturing and Quality Control Rules of Drugs and Quasi-Drugs (Ministerial Ordinance No. 16 of March 12, 1999) ("GMP") also apply to manufacture of products intended only for export.

- (d) **must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

A distribution license is required for any handling or sale of medicinal products. This requirement applies equally in respect of products intended for (re-)export.

3. **Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

The exemption from the product approval requirement only applies where the manufacturer/importer has filed a notification of manufacture/importation of medicinal products intended for (re-)export, and includes their destination.<sup>2</sup> If a notification is not filed, manufacture/importation of medical products without a product approval, as well as sale or handling of such products, is a criminal offence. The Japanese notion of "manufacturing" is very broad and includes "packaging."

It is consequently lawful for the licensee to import or domestically procure out-of-date medical products under the notification of (re-)exportation, re-package them as new products and export them to foreign destinations. Such practice would become unlawful only when the products have "decomposed" or are otherwise harmful.

The authorities will also issue a certificate of compliance with the Law, if requested by an exporter.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The Law makes no distinction between importation for manufacturing purposes and importation for trans-shipment. Therefore, trans-shipment of products is regulated in the same way as the import of product for "manufacturing" purposes and eventual re-export.

---

<sup>2</sup> Article 15 of the Enforcement Order states that the notification must be filed at least 3 months prior to commencement of manufacture/importation. One notification is sufficient for a series of shipments of the same product category.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

There are no reported events of enforcement action against exportation of medicinal products. However, it is likely that the regulatory agency would be less concerned about exported medicinal products than products intended for the Japanese market.

**Liechtenstein**

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The placing on the market, import and export of medicinal products is regulated by the Law Governing the Traffic of Medicinal Products within the EEA (*Gesetz über den Verkehr mit Arzneimitteln im Europäischen Wirtschaftsraum*, or “EWR-Heilmittelgesetz”) and its implementing regulation.<sup>1</sup>

Marketing authorizations, manufacturing and wholesale licenses are granted by the Board of Control for Medicinal Products (*Kontrollstelle für Arzneimittel*, or “Kontrollstelle”). The Kontrollstelle also conducts the necessary inspections.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to Article 9 of the EWR-Heilmittelgesetz, no medicinal product can be “placed on the market in Liechtenstein” without approval by the Kontrollstelle. The term “placing on the market” is defined as “the placing on the market for the first time by a manufacturer or wholesaler of a medicinal product for which the distribution, the dispensing and the administration must be approved, respectively the first placing on the market of a medicinal product that was approved in accordance with Regulation 2309/93.” A marketing authorization is therefore required before a product can be supplied or marketed in Liechtenstein.

The EWR-Heilmittelgesetz does not provide for exemptions. A strict interpretation of the law could therefore result in a marketing authorization being required to import products to be placed on the Liechtenstein market. A marketing authorization would not be required for medicinal products that are imported for subsequent re-export because these products would not be placed on the market in Liechtenstein.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

Section 30(2) of the EWR-Heilmittelgesetz requires that any person who manufactures a medicinal product hold a manufacturing license. The term “manufacturing” encompasses “the part or full manufacturing, the filling, the packaging, the labeling and the

---

<sup>1</sup> Products intended exclusively for the Swiss and the Liechtenstein market are covered by the Heilmittelgesetz. However, the free movement of goods principle does not apply to these products and so they cannot move freely within the EEA.

importation [of medicinal products] from non-EEA countries” (Section 30(1) of the EWR-Heilmittelgesetz).

A manufacturing license will be granted if the applicant has (i) suitable premises; (ii) the necessary technical equipment; and (iii) hired a qualified person.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Yes, according to section 32 of the EWR-Heilmittelgesetz, holders of a manufacturing license must comply with European GMP.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Section 35(2) of the EWR-Heilmittelgesetz requires that any person engaged in wholesaling hold a license. The term “wholesaling” encompasses “each activity which consists of purchasing, delivering, or exporting of medicinal products with the exception of the delivering of medicinal products to the public” (Section 35(1)). As a result, distributors and exporters must obtain a license.

The Regulation to the EWR-Heilmittelgesetz, which specifies requirements for obtaining a wholesale license, requires that the wholesaler follow good distribution practices (section 23(3)(k)).

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless a product contains a narcotic, psychotropic or other controlled substance, no pre-notifications or pre-approvals are required.

**4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

Trans-shipped products are not be covered by the EWR-Heilmittelgesetz because they are technically not “placed on the market” in Liechtenstein.

**5. If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a manufacturer’s or wholesale dealer’s license is required, the Kontrollstelle will conduct inspections prior to granting the license and on a regular basis thereafter. These inspections are intended to ensure that license holders comply with the conditions of their license, with the provisions of Liechtenstein law, and with GMP or

**COVINGTON & BURLING**

GDP as appropriate. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Luxembourg

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Law of August 4, 1975 on Manufacturing and Import (the "1975 Law"), Law of April 11, 1983 on Marketing and Advertising of Medicines (the "1983 Law"), Law of January 6, 1995 on Wholesale Distribution of Medicines (the "1995 Law"), and their implementing Grand Duke regulations provide the legislative basis for control of medicinal products through a system of licenses and authorizations. Amongst other things, unless an exemption applies, it is unlawful for medicinal products to be imported, marketed, manufactured, distributed, sold, supplied in, or exported from, Luxembourg, except in accordance with the appropriate approvals.

The Pharmacy and Medicines Department of the Ministry of Health issues licenses to those engaged in the manufacture, sale, or supply of medicinal products. It also conducts inspections to ensure that license holders comply with the terms of their licenses.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

A marketing authorization is required before a product can be imported into, supplied in, or exported from Luxembourg.

According to Article 3 of the 1983 Law, no medicinal product may be placed on the market unless the Ministry of Health has granted a marketing authorization. The term "placed on the market" is not expressly defined. However, Article 4 of the 1983 Law stresses that "selling, holding for sales, giving for free, or importing medicines" is prohibited unless authorized in Luxembourg.

Further, Article 2 of the 1995 Law provides that only medicines that are authorized may be distributed by wholesale dealing in Luxembourg. Article 1 of the 1995 Law defines "wholesale distribution" as any act of procuring, holding, supplying, or exporting medicines, except delivering medicines to the public.

- (b) **must manufacturers of such products hold a manufacturer's authorization?**

Article 3 of the 1975 Law requires an authorization from the Ministry of Health for the manufacture of medicinal products, whether or not it is intended for export.

Applicants for manufacturing authorizations must provide the Ministry of Health with detailed information about the production facilities and personnel qualifications. The Ministry of Health will only issue a manufacturer's authorization when it is satisfied that

the information contained in the application is accurate and in compliance with requirements of the legislation. This usually follows a site inspection.

Only wholesalers and manufacturers who are duly authorized may import medicinal products from non-EEA countries (Article 7 of the 1995 Law).

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

Authorized manufacturers must comply with the requirements of the Grand Duke decree of September 22, 1992. The decree requires that all manufacturing operations are conducted in accordance with the marketing authorization and with European GMP.

Where product is imported from a non-EEA country under a wholesaler or manufacturer's authorization, the importer (i.e., the wholesaler or manufacturer) must ensure that the manufacturing operations outside the EEA have been carried out by a duly authorized manufacturer; that the products have been manufactured and assembled in accordance with GMP; and that each production batch has undergone a full qualitative analysis, and a quantitative analysis of at least all the active ingredients. All associated testing and quality control operations must be conducted in accordance with European GMP.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Article 3 of the 1995 Law requires that all wholesalers of medicinal products obtain a wholesaler's authorization. Wholesale distribution includes any act of procuring, holding, supplying, or exporting medicines. However, Luxembourg authorities recognize manufacturer authorizations granted in other EU member states, under Directive 92/25 on Wholesale of Medicines. In addition, holders of a manufacturer's authorization are automatically authorized to distribute medicines.

Articles 4 and 5 of the 1995 Law require authorized wholesalers to comply with good distribution practices ("GDP"), set out at the EU level.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no government pre-notification or pre-approval requirements that must be fulfilled prior to the export of medicinal products. The Ministry of Health will issue export certificates on request to assist exporters in satisfying import requirements in other countries. However, Luxembourg does not require these certificates.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The 1995 Law repealed the legal provisions on imports contained in the 1975 Law and abolished the status of the importer. Consequently, no rules govern import in Luxembourg, other than those relating to wholesale distribution. However, according to an official in the Pharmacy and Medicines Department of the Ministry of Health, the provisions on import (but not the provisions on importers) of the 1975 Law are still applied.

Article 6 of the 1975 Law provides that imports must be authorized. It also provides that an import authorization may only be granted for medicines authorized in Luxembourg. If the products are imported into Luxembourg and then stored for export purposes, they are technically distributed in Luxembourg. In this case, a wholesaler or manufacturer authorization is required and the products must be authorized in Luxembourg.

However, no import authorization is required for transit operations. According to an official of the Pharmacy and Medicines Department of the Ministry of Health, the term "transit" is interpreted as "in customs" (*i.e.*, not in Luxembourg). As import authorizations have been replaced by wholesaler or manufacturer authorizations, Article 6 suggests that no authorization is required in order to import a trans-shipped (in transit) medicine. However, the Ministry of Health has never reached a decision on the situation of medicines that are simply transported through Luxembourg.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a Luxembourg manufacturer's or wholesaler's authorization is required, the Pharmacy and Medicines Department of the Ministry of Health will conduct inspections prior to the grant of the authorization and on a regular and repeated basis thereafter. These inspections are intended to ensure that authorization holders comply with the conditions of their license, with the provisions of Luxembourg law, and with GMP or GDP as appropriate. However, according to an official of the Pharmacy and Medicines Department, the Department does not have the material and human resources to enforce pharmaceutical laws as much as it should.

## Netherlands

1. **Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines Law of 28 July 1958 (*Wet op de Geneesmiddelenvoorziening*, or “the Law”) and the Decree on the Preparation and Dispensing of Medicinal Products of 8 September 1977 (*Besluit bereiding en aflevering van farmaceutische producten*, or “the Decree”) provide the legislative basis for the control of medicinal products through a system of licenses and authorizations. Amongst other things, it is unlawful for medicinal products to be imported, marketed, manufactured, distributed, sold, supplied in, or exported from, the Netherlands except in accordance with the appropriate approvals.

2. **If the laws in your jurisdiction apply to products intended only for export:**

- (a) **is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

A marketing authorization is not required if medicinal products are not intended to be marketed in the Netherlands. Under article 21.2 of the Decree on the Registration of Medicines of 8 September 1977 (*Besluit registratie geneesmiddelen*), the preparation and importation of medicines that will be marketed only outside the Netherlands are expressly excluded from the marketing authorization requirement.

According to an official, wholesaling for export purposes is not considered placing on the market and would not require a marketing authorization.

- (b) **must manufacturers of such products hold a manufacturer’s authorization?**

Article 2 of the Law, in combination with the Decree, requires that any person who manufactures or assembles a medicinal product hold a manufacturer’s license. This obligation applies to the manufacture or assembly of any medicinal product, even if it is intended only for export.

Applicants for manufacturing licenses must provide detailed information about the production and/or control of the pharmaceutical manufacturing operations to be carried out.

- (c) **must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Holders of a manufacturing license must comply with the requirements set out in part 2 of the Decree and the rules based on the Decree. These include a requirement that the license holder conducts all manufacture and assembly operations in accordance with European GMP.

- (d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

Article 2 of the Law, in combination with the Decree, requires that any person distributing medicinal products by way of “wholesale dealing” in the course of a business obtain a wholesale dealer’s license.<sup>1</sup> Distribution by way of wholesale dealing includes any act of selling or supply, as well as procuring, holding, or exporting a product for sale or supply.

Authorized wholesale dealers must fulfill the obligations in part 5 of the Decree. These include obligations to provide and maintain suitable staff, premises, equipment and facilities and to comply with good distribution practices (“GDP”). The current GDP requirements are set out in European Commission guidelines, and are intended to ensure that product quality is unaffected during storage and transportation.<sup>2</sup>

- 3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

No Dutch government pre-notification or pre-approval requirements must be fulfilled prior to the export of medicinal products, exception in the case of products containing a narcotic, psychotropic or other controlled substance. The inspection services will issue on request a manufacturing certificate confirming that a particular manufacturer possesses the necessary licenses.

- 4. Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The importation of finished medicinal products from outside the EU for re-export outside the EU requires an import license (which also covers subsequent export). Further, the holder of the importation license must comply with the requirements of part 4 of the Decree including European GMP and GDP.

If products remain under customs control in the Netherlands, the inspection services will not consider this to be an importation into the Netherlands. Therefore, no license is required and the requirements of the pharmaceutical legislation do not apply. However, it is possible that different regional inspection services would take a different approach.

---

<sup>1</sup> In the case of the manufacturer, the manufacturing license automatically also covers the sale of products.

<sup>2</sup> See <http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2001/may/GDPGuidelines1.pdf>.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

We are not aware of the extent to which the Dutch inspection services enforce the rules regarding products intended only for export. However, in general, Dutch inspection services are relatively active and would be concerned about products intended only for export as well as other products.

**New Zealand**

*Robert Bycroft*

*Chapman Tripp*

*Tel: +64 9 357 9012*

*Email: Robert.Bycroft@chapmantripp.com*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Medicines Act 1981 (“the Act”)<sup>1</sup> and the Medicines Regulations 1984 (“the Regulations”), primarily control the quality, safety and efficacy of products intended for sale in New Zealand. They also place a number of restrictions on the importation, manufacture, and distribution of products intended for export.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

It is an offense under section 20 of the Act to sell, distribute in any way, or advertise the availability of a medicine before the Minister of Health has consented to the distribution of the medicine. The Act does not expressly address the exporting of a medicine before approval by the Minister of Health.

However, an exporter of an unapproved medicine may commit an offence under section 20 of the Act by undertaking export-related activities in New Zealand prior to export, such as advertising the availability of the medicine or distributing it in any way.

- (b) must manufacturers of such products hold a manufacturer’s authorization?**

According to section 17 of the Act, any person in the business of manufacturing, packing, or labeling of a medicine must be licensed, whether the medicine is intended for export or not.

The Act does not expressly prohibit the export of products made by an unlicensed manufacturer. However, under section 63 of the Act, the New Zealand regulatory authorities have the power to seize or detain any product in relation to which an officer reasonably believes an offence against the Act has been committed. This provision could potentially be used to prevent the export of medicines made by an unlicensed manufacturer.

---

<sup>1</sup> New Zealand legislation is available online at: [www.legislation.govt.nz](http://www.legislation.govt.nz).

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices (“GMP”)?**

Exported products are not expressly required to be manufactured in accordance with New Zealand’s standards of GMP, and a license is not generally required for the export of medicines that may be legally sold in New Zealand.

However, where a medicine is being both exported from and distributed in New Zealand, the medicine should be manufactured in accordance with New Zealand’s GMP, because:

- (i) the Minister of Health requires evidence of the quality, safety, and efficacy of a medicine, as well as certification that it is manufactured in accordance with GMP, as part of the process of approving a new medicine (Section 21(2)); and
- (ii) the Act provides that importers or manufacturers must not sell, distribute in any way, or advertise for sale any medicine unless they possess details of specifications for quality testing of that medicine and a certificate of the test results of every batch of that medicine distributed or to be distributed in New Zealand (Section 42).

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

The Act generally prohibits the importation, procuring, receiving, storing, use, or possession of any prescription medicine unless:

- (i) the person performing those acts is licensed or otherwise authorized under the Act to manufacture, sell, supply, pack, or administer the medicine or to possess it; and
- (ii) the act is necessary or incidental to the business, calling, or purpose for which the person is so licensed or authorized (Section 43).

However, according to section 33 of the Act, a license is not generally required to export a medicinal product (other than a prescription medicine or a controlled drug) if the product could be lawfully sold by a pharmacist to a person in New Zealand at the time of export. For example, no license is required to export medicines which have been approved for distribution in New Zealand.

**3. Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

No government pre-notification or pre-approvals are required unless the medicines are also controlled drugs under the Misuse of Drugs Act.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The Act does not expressly regulate the trans-shipment of medicines or the importation of medicines for re-export from New Zealand. The main controls on the importation of medicines are focused on domestic distribution.

Once a product is in New Zealand, it is subject to the Act's general controls regarding the quality, safety and efficacy of the medicines that are stored or sold in New Zealand. For example:

- (i) the Director-General of Health and Minister of Health has general powers in relation to any medicine (other than a new medicine) that he has reason to believe may be unsafe or ineffective for the therapeutic purpose for which it is sold (Section 36);
- (ii) the Regulations give the Director-General of Health the power to order importers, manufacturers or sellers to withdraw from sale, and dispose of, any medicines where he considers it necessary to protect the public or where the medicines do not conform to specification (Regulation 50);
- (iii) the Regulations require that medicines are stored in a manner that minimizes their deterioration (Regulation 32).

The above provisions are not expressly limited to products intended for distribution in New Zealand and could potentially be used to restrict the export of specific medicines if quality issues are identified.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

Given the generally limited and uncertain nature of New Zealand's legislative controls on the export of pharmaceuticals, New Zealand regulatory authorities focus their enforcement efforts on activities within New Zealand that breach the Act or Regulations, as well as on Internet pharmacies and the export of controlled drugs.

In an "off the record" discussion, an official with MedSafe, the division of the Ministry of Health responsible for administering the Act, Regulations and the Misuse of Drugs Act 1975, indicated that MedSafe is aware of some licensed wholesalers exporting medicines from New Zealand. However, MedSafe's enforcement in relation to such activities generally is limited to:

- (i) advising those wholesalers to comply with the laws of the country of export; and

- (ii) responding to specific complaints received from overseas jurisdictions about the quality of medicines exported from New Zealand.

## Norway

*Aase Gundersen*

*Bugge, Arentz-Hansen & Rasmussen*

*Tel: +47 22 83 02 70*

*Email: aag@bahr.no*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

The Act of 4 December 1992 no. 132 relating to medicines etc. ("the Medicinal Act") provides the legislative basis for control of medicinal products through a system of licenses and authorizations. In addition, a number of regulations contain provisions relevant for medicinal products intended for export only. These are:

- (i) Regulation of 22 December 1999 on medicinal products (hereinafter referred to as "the Regulation");
- (ii) Regulation of 21 December 1993 on pharmaceutical wholesaling (the "Wholesale Regulation"); and
- (iii) Regulation of 30 June 1993 on manufacturing and import of medicinal products (the "Manufacturing Regulation").

Medicinal products may only be imported, marketed, manufactured, distributed, sold, supplied in, or exported from Norway in accordance with the required approvals and with the conditions set forth in the regulations.

The Norwegian Medicines Agency ("the Agency") is the national regulatory authority for approval and surveillance of pharmaceutical products in Norway. Its duties include the issuance of licenses to those engaged in the manufacture, sale, or supply of medicinal products and the conduct of inspections to ensure that license holders comply with the legislation.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to section 8 of the Medicinal Act and Section 3-1 of the Regulation, a medicinal product cannot be placed on the Norwegian market unless the Agency (or the European Commission) has granted a marketing authorization for that product. Because mere importation of a product does not place the product on the market, no marketing authorization is required to import a medicinal product.

No particular rules apply for medicinal products intended only for export. The rules concerning marketing authorizations that apply to domestic medicinal products apply equally to products intended for export only.

**(b) must manufacturers of such products hold a manufacturer's authorization?**

According to section 3(1) of the Manufacturing Regulation, any person who manufactures<sup>1</sup> a medicinal product must hold a manufacturer's license. This provision explicitly states that manufacturing licenses are also required for medicinal products that are intended for export only.

Applicants for manufacturing licenses must substantiate that the requirements of the Manufacturing Regulation are met. The Agency will only issue a manufacturer's license when it is satisfied that the information contained in the application is accurate and in compliance with the legal requirements.

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

According to Section 5 of the Manufacturing Regulation, all manufacturing operations must be conducted in accordance with European GMP. The license holder must conduct all manufacturing and assembly operations in a way that ensures conformity with the standards of strength, quality, and purity applicable under the relevant marketing authorization.

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

The term "wholesaling" includes all activities necessary for procurement, warehousing, distribution, and export of pharmaceuticals other than distribution to the public. Any person intending to carry out a wholesaling business must obtain a wholesaling license from the Agency (section 14 of the Medicinal Act).

Those with manufacturer's licenses or import licenses, issued under with sections 12 and 13, respectively, of the Medicinal Act, do not also need a wholesaling license to conduct wholesaling activities in respect of the products that are included in their manufacturing or importing licenses. Further, companies with manufacturer's licenses issued by another country within the EEA may also engage in wholesaling activities for those products specified in the manufacturer's license (section 3 of the Wholesale Regulation).

Authorized wholesale dealers, manufacturers, and importers must fulfill various obligations in order to ensure the quality and safety of products. One of these requirements is that wholesalers comply with good distribution practices ("GDP"), as set out by the European Commission.

---

<sup>1</sup> The term "manufacturing" is defined in Section 1 to include manufacturing, packing, re-packing, re-labeling and releasing of medicinal products, and the required testing and control operations in connection with said activities.

3. **Does the export of medicines from your jurisdiction require any government pre-notification or pre-approval?**

Unless the product contains a narcotic, psychotropic or other controlled substance, there are no pre-notification or pre-approval requirements that must be fulfilled prior to exporting medicinal products.

4. **Do the laws in your jurisdiction apply to products that are imported solely for subsequent export from your jurisdiction, i.e. where products are merely trans-shipped across your jurisdiction? If such products are regulated, in what way, if any, does their regulation differ from that for products intended only for export?**

The legislation does not exempt medicinal products that are imported to Norway solely for subsequent export. Thus, the trans-shipment of products *via* Norway is subject to relevant license requirements and to Agency supervision.

5. **If your national rules are applied to products that are intended only for export or trans-shipment, do you know the extent to which regulators in your jurisdiction actively enforce these rules?**

To the extent that a Norwegian manufacturing, import, or wholesale dealer's license is required, the Agency shall, prior to the grant of the license, undertake all required inspections to ensure that the applicant complies with the conditions of the license, Norwegian law, and with European GMP or GDP, as appropriate. Licenses issued by the Agency can be withdrawn for noncompliance with the relevant obligations. There is no evidence to suggest that inspections or enforcement activities are less rigorous when products are intended only for export.

## Portugal

*Joaquim Caimoto Duarte*

*Vasconcelos, F. Sá Carneiro, Fontes & Associados*

*Tel: +351 210 308 600*

*Email: Joaquim.CaimotoDuarte@vscf.net*

- 1. Do the laws in your jurisdiction regulate the import, manufacture, distribution, supply or shipment of medicines intended only for export from your jurisdiction? If they do, please provide citations of the relevant provisions.**

Decree-Law 72/91, of February 8, 1991 ("the Medicines Act"); Decree-Law 135/95, of June 9, 1995 on wholesale distribution of medicinal products for human use ("Decree-Law 135"); and the Directorate-General for Customs's Guidelines ("Circular") No. 46/2000 and 55/2000, on import/export of medicines ("the Import/Export Guidelines") are the basic legislation for the import, manufacture, distribution, supply, and shipment of medicines intended for export. There is no specific legislation on the handling of medicines intended only for export.

- 2. If the laws in your jurisdiction apply to products intended only for export:**

- (a) is a marketing authorization required before they can be imported, supplied, or exported? If a marketing authorization is required, do the authorization and approval process and the standards that are applied differ from those for products intended for your domestic market?**

According to the Medicines Act and Decree-Law 135, a medicinal product cannot be supplied or marketed in Portugal unless a marketing authorization or a special authorization has been granted by INFARMED (the Portuguese pharmaceutical regulatory authority) or the EU.

According to the Import/Export Guidelines, marketing authorization is not required prior to the mere act of import, if the product is not to be supplied or marketed in Portugal. Export requires evidence of marketing or manufacturing authorization issued by INFARMED. If the product was not manufactured in Portugal and market authorization was not granted by INFARMED, evidence of marketing or manufacturing authorization by the appropriate authorities in the source country is required, instead. Prior to export, the exporting entity must exhibit to the customs office evidence of a relevant market or manufacturer license. The Directorate-General for Customs also requires evidence of the acceptance of the relevant medicinal product in the destination country.

- (b) must manufacturers of such products hold a manufacturer's authorization?**

All manufacturers of pharmaceutical products must hold a manufacturer's authorization, whether the products are intended for export or not. Any type of manufacturing, including division, packaging, and layout of medicinal products, is subject to this special authorization. The holder of this authorization must have qualified technicians, must

trade only those products for which he has authorization, and must follow the applicable EC framework on good manufacturing practices (GMP).

**(c) must products intended only for export be manufactured in accordance with good manufacturing practices ("GMP")?**

According to the Medicines Act and Ruling (*Portaria*) 42/92, of January 23, 1992 (the Portuguese legislation on GMP, "Ruling 42"), holders of a manufacturing license must comply with GMP requirements, established in Portugal in accordance with the European Commission guidelines.

For products imported from outside the EEA, the license holder must ensure that the manufacturing has been carried out by a duly authorized manufacturer subject to GMP at least equivalent to the EC guidelines (Ruling 42).

**(d) must distributors or exporters of such products hold a government authorization and must good distribution practices be followed?**

According to Decree-Law 135 and the Import/Export Guidelines, wholesale distributors or exporters must hold a license issued by INFARMED for wholesale distribution or for the export activity.

Decree-Law 135 considers "wholesale distribution of medicines for human use" to include any commercial activity that encompasses the stocking, possession, or supply of medicines for human use destined for transformation, re-selling, or usage by medical services, health units, and pharmacies. It does not include supply to the general public. As described above, this commercial activity must be approved by INFARMED. However, the following distribution activities are exempted from this approval requirement:

- (i) distribution of self-manufactured medicines by an entity with a manufacturing license; and
- (ii) any distribution activity conducted by a wholesaler duly licensed by another country of the EC that does not possess wholesale facilities in Portugal.

All distribution activity conducted in Portugal (including activity subject to a proper wholesaling license, specially exempted activity, and mere exporting activity) must comply with good distribution practices ("GDP"). Ruling (*Portaria*) 348/98, of June 15, 1998 ("Ruling 348") establishes the Portuguese legal framework for GDP, in accordance with EC guidelines.

Export activity by an entity which does not have a wholesaling license or a special exemption for the referred activity should also comply with the applicable GDP.